



AN EXPLANATION OF STANDARDIZED PROCEDURE REQUIREMENTS FOR NURSE PRACTITIONER PRACTICE

Standardized Procedures are authorized in the Business and Profession Code, Nursing Practice Act (NPA) Section 2725 and further clarified in California Code of Regulation (CCR 1480). Standardized procedures are the legal mechanism for registered nurses, nurse practitioners to perform functions which would otherwise be considered the practice of medicine. Standardized procedures must be developed collaboratively by nursing, medicine, and administration in the organized health care system where they will be utilized. Because of this interdisciplinary collaboration for the development and approval, there is accountability on several levels for the activities to be performed by the registered nurse, nurse practitioner.

Organized health care systems includes health facilities, acute care clinics, home health agencies, physician's offices and public or community health services. Standardized procedures means policies and protocols formulated by organized health care systems for the performance of standardized procedure functions.

The organized health care system including clinics, physician's offices (inclusive of sites listed above) must develop standardized procedures permitting registered nurse, nurse practitioner to perform standardized procedure functions. A registered nurse, nurse practitioner may perform standardized procedure functions only under the conditions specified in a health care system's standardized procedure; and **must provide the system with satisfactory evidence that the nurse meets its experience, training, and/or education requirements to perform the functions.**

A nurse practitioner is a registered nurse who possesses additional preparation and skill in physical diagnosis, psycho-social assessment, and management of health-illness needs in primary health care, and who has been prepared in a program conforming to the Board standards as specified in CCR 1484 (Standards of Education).

The Board of Registered Nursing has set educational standards for nurse practitioner certification which must be met in order to "hold out" as a nurse practitioner. Nurse practitioners who meet the education standards and are certified by the BRN are prepared to provide primary health care, (CCR 1480 b), that which occurs when a consumer makes contact with a health care provider who assumes responsibility and accountability for the continuity of health care regardless of the presence or absence of disease.

Scope of Medical Practice

The Medical Practice Act authorizes physicians **to diagnose** mental and physical conditions, **to use drugs in or upon** human beings, **to sever or penetrate the tissue** of human beings and **to use other methods** in the treatment of diseases, injuries, deformities or other physical or mental conditions. As a general guide, the performance of any of these functions by a registered nurse, nurse practitioner requires a standardized procedure.

Standardized Procedure Guidelines.

The Board of Registered Nursing and the Medical Board of California jointly promulgated the following guidelines. (Board of Registered Nursing, Title 16, California Code of Regulations (CCR) section 1474; Medical Board of California, Title 16, CCR Section 1379.)

- (a) Standardized procedures shall include a written description of the method used in developing and approving them and any revision thereof.
- (b) Each standardized procedure shall:
 - (1) **Be in writing, dated and signed by the organized health care system** personnel authorized to approve it.
 - (2) Specify **which standardized procedure functions** registered nurses may perform and under what circumstances.
 - (3) State any specific **requirements which are to be followed** by registered nurses in performing particular standardized procedure functions.
 - (4) Specify any **experience, training, and/or education** requirements for performance of standardized procedure functions.
 - (5) Establish a method for initial and continuing **evaluation** of the competence of those registered nurses authorized to perform standardized procedure functions.
 - (6) Provide for a method of maintaining a written record of those **persons authorized to perform** standardized procedure functions.
 - (7) Specify the scope of **supervision** required for performance of standardized procedure functions, for example, telephone contact with the physician.
 - (8) Set forth any specialized circumstances under which the registered nurse is to immediately **communicate with a patient's physician** concerning the patient's condition.
 - (9) State the limitations on **settings**, if any, in which standardized procedure functions may be performed.
 - (10) Specify patient **record-keeping** requirements.
 - (11) Provide for a method of **periodic review** of the standardized procedures.

An additional safeguard for the consumer is provided by steps four and five of the guidelines which, together, form a **requirement that the nurse be currently capable** to perform the procedure. If a RN or NP undertakes a procedure without the competence to do so, such an act may constitute gross negligence and be subject to discipline by the Board of Registered Nursing.

Standardized procedures which reference textbooks and other written resources in order to meet the requirements of Title 16, CCR Section 1474 (3), must include book (specify edition) or article title, page numbers and sections. Additionally, the standards of care established by the sources must be reviewed and authorized by the registered nurse, physician and administrator in the practice setting. A formulary may be developed and attached to the standardized procedure. Regardless of format used, whether a process protocol or disease-specific, the standardized procedure must include all eleven required elements as outlined in Title 16, CCR Section 1474.

SUGGESTED FORMAT FOR STANDARDIZED PROCEDURES

I. POLICY

1. Function(s): (2)*
2. Circumstances under which R.N. may perform function: (2)
 - a. Setting (9)
 - b. Supervision (7)
 - c. Patient Conditions
 - d. Other

II. PROTOCOL (3)

1. Definitions
2. Data base
 - a. Subjective
 - b. Objective
3. Diagnosis
4. Plan
 - a. Treatment
 - b. Patient conditions requiring consultation (8)
 - c. Education - patient/family
 - d. Follow up
5. Record keeping (10)

III. REQUIREMENTS FOR REGISTERED NURSE: (4)(5)

1. Nurse practitioner education program, specialty
2. Advance level training
3. Experience as a nurse practitioner
4. National Certification in a specialty
5. Method of initial and continuing evaluation of competence

IV. DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE

1. Method: (Title 16, CCR Section 1474(a))
2. Review schedule (11)
3. Signatures of authorized personnel approving the standardized procedure, and dates: (1)
 - a. Nursing
 - b. Medicine
 - c. Administration

V. REGISTERED NURSES AUTHORIZED TO PERFORM PROCEDURE AND DATES (6)

- 1.
- 2.

*** Numbers in parentheses correspond to Board of Registered Nursing guideline numbers in Title 16, CCR Section 1474.**

EXAMPLE A (Process Protocol)

The Board of Registered Nursing does not recommend or endorse the medical management of this sample standardized procedure. It is intended as a guide for format purposes only.

Standardized Procedures

General Policy Component

I. Development and Review

- A. All standardized procedures are developed collaboratively and approved by the Interdisciplinary Practice Committee (IDPC) whose membership consists of nurse practitioners, nurses, physicians, and administrators and must conform to all 11 steps of the standardized procedure guidelines as specified in Title 16, CCR Section 1474.
- B. All standardized procedures are to be kept in a manual which includes dated, signed approval sheets of the persons covered by the standardized procedures.
- C. All standardized procedures are to be reviewed every three years and as practice changes by the IDPC.
- D. All changes or additions to the standardized procedures are to be approved by the IDPC accompanied by a dated and signed approval sheet.

II. Scope and Setting of Practice

- A. Nurses may perform the following functions within their training specialty area and consistent with their experience and credentialing: assessment, management, and treatment of episodic illnesses, chronic illness, contraception, and the common nursing functions of health promotion, and general evaluation of health status (including but not limited to ordering laboratory procedures, x-rays, and physical therapies, recommending diets, and referring to Specialty Clinics when indicated).
- B. Standardized procedure functions, such as managing medication regimens, are to be performed in (list area, i.e., short appointment clinic). Consulting physicians are available to the nurses in person or by telephone.
- C. Physician consultation is to be obtained as specified in the individual protocols and under the following circumstances:
 - 1. Emergent conditions requiring prompt medical intervention after initial stabilizing care has been started.
 - 2. Acute decompensation of patient situation.
 - 3. Problem which is not resolving as anticipated.
 - 4. History, physical, or lab findings inconsistent with the clinical picture.
 - 5. Upon request of patient, nurse, or supervising physician.

III. Qualifications and Evaluations

- A. As described in the General Policy Component.
- B. Covers only those registered nurses as identified in General Policy Component.

II. Protocol

- A. **Definition:** This protocol covers the management of common primary care conditions seen in the outpatient setting, such as eczema, headaches, acne, fatigue syndromes, allergic rhinitis, and low pain.
- B. **Database** - Nursing Practice
(Perform usual total nursing assessment to establish data base).
- C. **Treatment Plan** - Medical Regimen
 - 1. **Diagnosis**
 - a. Most consistent with subjective and objective findings expected by patient. If diagnosis is not clear, assessment to level of surety plus differential diagnosis.
 - b. Assessment of status of disease process when appropriate.
 - 2. **Treatment** - (Common nursing functions)
 - a. Further lab or other studies as appropriate.
 - b. Physical therapy if appropriate.
 - c. Diet and exercise prescription as indicated by disease process and patient condition.
 - d. Patient education and counseling appropriate to the disease process.
 - e. Follow-up appointments for further evaluation and treatment if indicated.
 - f. Consultation and referral as appropriate.
 - 3. **Physician Consultation:** As described in the General Policy Component.
 - 4. **Referral to Physician or Specialty Clinic:** Conditions for which the diagnosis and/or treatment are beyond the scope of the nurse's knowledge and/or skills, or for those conditions that require consultation.
 - 5. **Furnishing Medications** - (Medical Regimen)
Follow furnishing protocol, utilizing formulary.

PROTOCOL: DRUGS AND DEVICES

Definition: This protocol covers the management of drugs and devices for women of all ages presenting to _____ clinic. The nurse practitioner may initiate, alter, discontinue, and renew medication included on, but not limited to the attached formulary. All Schedule I and Schedule II drugs are excluded.

Subjective Data: Subjective information will include but is not limited to:

- 1. Relevant health history to warrant the use of the drug or device.
- 2. No allergic history specific to the drug or device.
- 3. No personal and/or family history which is an absolute contraindication to use the drug or device.

Objective Data: Objective information will include but is not limited to:
NPR-B-20 12/1998

1. Physical examination appropriate to warrant the use of the drug or device.
2. Laboratory tests or procedures to indicate/contraindicate use of drug or device if necessary.

Assessment: Subjective and objective information consistent for the use of the drug or device. No absolute contraindications of the use of the drug or device.

Plan: Plan of care to monitor effectiveness of any medication or device.

Patient Education: Provide the client with information and counseling in regard to the drug or device. Caution client on pertinent side effects or complications with chosen drug or device.

Consultation and/or Referral: Non-responsiveness to appropriate therapy and/or unusual or unexpected side effects and as indicated in general policy statement.

REFERENCES: PDR '94 50th Edition (list page)
 Primary Care Medicine, 3rd Edition, Chapter (list), pp. (list)
 Handbook of Gynecology and Obstetrics, 3rd Edition, Chapter (list),
 pp. (list)

FORMULARY

To include but not limited to those medications listed below:

Antibiotic: Ampicillin, Penicillin, Amoxicillin, Dicloxacillin, Augmentin, Keflex, Tetracycline, Noroxin, Minocin, Vibramycin, Benemid, Macrochantin, Erythromycin, Rocephin, Gantrisin, Trimethoprim/sulfamethoxazole, Nitrofurantoin, Nalidixic acid.

Antidiarrheal: Imodium, Donnagel

Antiemetic: Trans-derm V, Compazine, Phenergan, Tigan

Antifungal: Mycostatin oral suspension/tablets, Nizoral, Monistat, Femstat, Terazol, Gyne-Lotrimin

Antiviral: Zovirax ointment/capsules, Podophyllin 25-75%, Trichloroacetic acid

Antiparasite: Flagyl/Protostat, Kwell lotion/shampoo, RID lotion, Eurax cream

Biologic: RhoGAM, HypRho-D

Chemotherapeutic: 5FU for vaginal or vulvar use

Devices: Diaphragm, cervical cap, IUD, pessary, Norplant

Diuretic: Spironolactone, Dyazide

Hormone: All oral contraceptives, progesterone preparations, Estrogen (Premarin, Estinyl, Delestrogen, Estrovis, Estrace), Estraderm, Progestins (Aygestin, Provera, Micronor, Nor QD, Ovrette), Estrogen vaginal creams (Premarin, Estrace)

Local anesthetic: Xylocaine Jel 2%, Xylocaine 1% injection

Nonsteroidal Anti-inflammatory: Anaprox, Anaprox DS, Suprol, Motrin, Ponstel, Naprosyn, Rufen

Over the counter: Spermicidal agents, cold & cough preparations (non-narcotic), laxatives, stool softeners, antacids, antiflatulents, analgesics, prostaglandin inhibitors, topicals, vitamin/mineral, antihistamines, decongestants, hemorrhoidal/antidiarrheal.

Rectal: Anusol HC, Wyanooids
Thyroid: Synthroid, Armour thyroid tablets
Urinary analgesic: Pyridium
Vaginal: All appropriate antifungals, Aminocervical cream, Acijel, Betadine, Triple Sulfa cream, Estrogen cream.
Vitamin/Mineral: Prenatal vitamins, iron pill

EXAMPLE B (Disease Specific)

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Standardized Procedures

DEPARTMENT: _____ FACILITY: _____

POLICY

I. FUNCTIONS NURSE PRACTITIONERS MAY PERFORM:

Provide care for patients with acute conditions as covered in attached protocol (see sample attached) and furnish non-controlled drugs and devices to essentially healthy patients.

II. CIRCUMSTANCES UNDER WHICH NURSE PRACTITIONERS MAY PERFORM THESE FUNCTIONS:

A. May furnish non-controlled drugs and devices under standardized procedures under the supervision of a designated physician (or designee).

B. Applies to nurse practitioners working in (indicate departments involved).

III. EXPERIENCE, TRAINING AND/OR EDUCATION REQUIRED OF THE NURSE PRACTITIONER:

Maintains a current California license to practice as an RN, is certified by the State of California as a Nurse Practitioner, has met all the requirements for and has a current Furnishing Number issued by the Board of Registered Nursing. Is oriented to the facility.

IV. METHOD OF INITIAL AND CONTINUED EVALUATION OF COMPETENCE:

General competency is initially evaluated during the probationary period through a proctoring process by the supervising physician. The registered nurse is assigned to and is supervised by a designated physician who is responsible to annually evaluate appropriateness of practice and clinical decision making. A QA review process is established to assure that compliance to standards relating to important aspects of care are maintained.

V. DOCUMENTATION

Documentation required is outlined in each protocol. Patient specific documentation is entered into the patient's medical record.

DEVELOPMENT AND APPROVAL OF THE STANDARDIZED PROCEDURE

I. THIS STANDARDIZED PROCEDURE WAS:

Developed by the supervising physician, or designee, and the Nurse Practitioner. Approved by the department Chief, Director of Nursing Practice, Physician-in-Chief or designees, and Medical Group Administrator.

II. THIS STANDARDIZED PROCEDURE WILL BE REVIEWED AT LEAST ANNUALLY.

REVISION DATED _____ REVIEWED DATED _____

III. THE STANDARDIZED PROCEDURE WAS APPROVED BY:

MEDICINE _____ DATE _____
(Chief of Department)

MEDICINE _____ DATE _____
(PIC/Designee)

NURSING _____ DATE _____
(Director of Nursing Practice)

ADMINISTRATION _____ DATE _____
(Medical Group Administrator)

IV. PRACTITIONERS FUNCTION UNDER THIS STANDARDIZED PROCEDURE:

Current list of authorized personnel are on file in the office of the Medical Group Administrator and department manager.

PROTOCOLS (List those applicable)

I.E., Urinary Tract Infection (see attached).
Respiratory tract infection
Otitis Media
Vaginitis

References: List

URINARY TRACT INFECTION PROTOCOL: INITIAL VISIT

I. RATIONALE

This protocol will assist in the differentiation between pyelonephritis and urinary tract symptoms sufficiently to eradicate the symptoms per se rather than attempt to eradicate any bacteriuria that may or may not be present. The design of the protocol for UTI encompasses these principles.

II. SYMPTOMS

A. CYSTITIS

1. **FEMALE PATIENTS**

Order a STAT CVMS UA for female patients with any of the following symptoms;

- a. Dysuria
- b. Frequency
- c. Urgency
- d. Inability to empty bladder completely

2. Male patients

Male patients with any of the above symptoms should be seen by an M.D., not by a NP, unless they have a urethral discharge (possible VD - follow VD protocol).

B. PYELONEPHRITIS

1. In addition to the above symptoms, patients with pyelonephritis may have:

- a. Fever greater than 100.0 F. or
- b. Flank pains, or
- c. Chills, or
- d. Nausea, vomiting or abdominal pain.

2. Continue with protocol through the physical exam with these patients, but then consult supervising physician before deciding on treatment.

III. HISTORY

A. Consult supervising physician if patient has:

1. A history of kidney problems, or
2. Is currently pregnant. To ascertain this, always ask for LMP date and record for all female patients.
3. Diabetes or insulin.
4. Three or more UTIs in past 12 months

B. Continue with UTI protocol, but also refer patient to GYN if history of:

1. Vaginal discharge, or
2. Perineal inflammation.

IV. PHYSICAL EXAM

A. Perform the following examinations:

1. Abdominal
2. CVA
3. Temperature

B. Consult supervising physician if findings of:

1. Fever greater than 100.0 F. or
2. CVA tenderness.

V. LAB TESTS

INITIAL URINALYSIS

A. Consult supervising physician if:

1. Casts
2. RBCs or protein are positive (without associated WBC abnormality).

- B. If UA shows 10 or more WBCs/hpf and patient is symptomatic, give patient antibiotic prescription as described in the treatment section.
- C. If UA revealed 0-10 WBCs, review symptoms. If the symptoms are definite and very severe, treat with antibiotics; if symptoms are vague and poorly defined, then give patient symptomatic treatment as described in the treatment section and consider referral to GYN for pelvic.
- D. Should the initial UA be "positive": (defined in guidelines below), then give patient a repeat UA slip for the abnormality found with instructions to have that UA one week following completion of treatment.

Positive UA findings are defined as:

Casts: any except occasional hyaline or rare granular
 RBCs > 3 (if not menstruating) and WBC < 5
 Protein > trace and WBC < 5

VI. TREATMENT

ANTIBACTERIAL TREATMENT

To be given if initial UA reveals 10 or more WBC/hpf, or in any case where symptoms are severe, even if UA revealed, WBC/hpf.

- A. Prescribe appropriate antibiotic drug (see p.6)
- B. Instruct patient to call in if symptoms do not subside within 72 hours. If patient does call back, information for treatment failure instructions.

SYMPTOMATIC TREATMENT

To be given only if initial UA reveals, 10WBC/Hpf, and patient has minimal or uncertain symptoms. Consider GYN referral for pelvic.

- A. Prescribe either Propantheline 15 mg #20 sig: 1-2 QID prn or Belladonna with Pb tabs #15, sig: 1 tab QID prn.
- B. Instruct patient to call in if symptoms persist beyond 72 hours or if symptoms worsen at any time.

VII. REPEAT URINALYSIS (CVMS)

- A. Consult supervising physician if UA shows casts.
- B. If repeat UA confirms abnormality (protein and/or RBC as listed below) refer to Proteinuria and/or Hematuria protocols.

Positive UA findings are defined as:

Casts: any, except occasional hyaline or rare granular
 RBCs >3 (if not menstruating) and WBC <5
 Protein > trace and WBC <5

UTC PROTOCOL: ANTIBIOTIC TREATMENT

- A. If organism found in patient's urine is not listed in the table below, consult supervising physician for treatment.
- B. If this is the first antibiotic course (initial visit), assume E coli and use the first listed drug to which patient is not allergic, as listed for E coli in the drug table below.
- C. If this is a second antibiotic course (treatment failure), go to the first drug for the organism listed that is not the same as that previously used and to which the patient is not allergic. If the patient is allergic to all drugs listed, consult supervising physician for treatment.
- D. Prescribe according to the prescription table which follows:
 - 1. If symptoms have been present within the past 48 hours, use 1 dose treatment.
 - 2. If symptoms have been present longer than 48 hours, use 5-day treatment.
 - 3. If symptoms persists after treatment with first drug, repeat UA and culture and consult supervising physician.

UTI PROTOCOL: TREATMENT FAILURE

If the patient calls in with persisted or recurrent symptoms after the first course of antibiotic treatment, obtain a CVMS urine specimen for UA and culture and sensitivity.

If the UA is negative, wait for the culture results before treating. If the UA is positive, treat with the next drug listed on the Antibiotic Prescription Table and review treatment choice when the culture and sensitivity results are available.

If culture is positive and patients symptoms are improving, stay with the same antibiotic. If not responding after 3 days, switch to a new antibiotic based on culture sensitivity.

Adapted from protocol developed by: _____, NP

_____, MD

(List names of nurse practitioners and physicians who developed the standardized procedure, including the protocol section).

ANTIBIOTIC PRESCRIPTION TABLE

ORGANISM	DRUG
E. Coli Proteus mirabilis	Septra DS, Amoxicillin Macrochantin, Keflex
Aerobacter Klebsiella	Septra DS, Macrochantin Keflex, Ciprofloxacin
Enterococcus	Ampicillin *Consult MD if allergic
Pseudomonas	Ciprofloxacin (Usually not seen in out-patient setting)
DOSAGES	
SEPTRA DS	#3 PO at once or 1 bid x 5 days
AMOXICILLIN	500mg 3gms PO at once or 250mg 1 tid x 5 days
MACRODANTIN	100mg qid x 5 days
KEFLEX	250mg qid x 5 days
CIPROFLOXACIN	250mg qid x 5 days

EXAMPLE C (Procedure Specific)

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Standardized Procedure for Dispensing by Registered Nurse

I. Policy

- A. Drugs and devices listed in the agency formulary and prescribed by a lawfully authorized prescriber may be dispensed.
- B. Setting - Adult Clinic.
- C. Supervision - None required at the time of dispensing.

II. Protocol

A. Data Base

- 1. No patient or family history contraindications.
- 2. Agency required tests and procedures relative to the drug or device being dispensed demonstrate no contraindications.

B. Action

- 1. Affix label which contains information that follows.
 - a. Agency name, address and telephone number.
 - b. Patient's name.
 - c. Name of the prescriber and initials of the dispenser.
 - d. Date dispensed.
 - e. Trade or generic name of dispensed drug.
 - f. Quantity and strength of dispensed drug.
 - g. Directions for use of dispensed drug.
 - h. Expiration date of the drug's effectiveness.
- 2. Affix any appropriate auxiliary labels.
- 3. Use child proof containers.
- 4. Provide patient with appropriate information including:
 - ◆ directions for taking the drug;
 - ◆ what to do and whom to contact if side effects occur;
 - ◆ common side effects;
 - ◆ possible serious or harmful effects of the drug; and
 - ◆ any manufacturer-prepared information required by the FDA.

C. Record Keeping - Document in the patient record:

- 1. Name, dosage, route and amount of the drug dispensed.
- 2. Lot number and manufacturer's name.
- 3. Other information, including patient instructions given.
- 4. Complete information in the pharmacy dispensing log.

D. Consultation - Contact the prescriber if the item is not listed in the agency formulary for RN dispensing or regarding contraindications.

III. Requirements for Registered Nurses

- A. Education, training and experience: successful completion of the agency's in-service program on dispensing.
- B. Initial evaluation: Demonstration of competency in skill performance to the satisfaction of the Pharmacy Director.
- C. On-going evaluation - Monthly random record review by the pharmacist and an annual performance appraisal including observation of dispensing.

IV. Development and Approval of the Standardized Procedure

This standardized procedure was approved by the following:

NURSING _____ DATE _____

MEDICINE _____ DATE _____

PHARMACY _____ DATE _____

ADMINISTRATION _____ DATE _____

The standardized procedure will be reviewed annually.

V. RNs authorized to perform the procedure.

1. _____ DATE _____

2. _____ DATE _____