California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

Licensing Committee Report

Ruth Conroy, Pharm.D., Chair
Richard Benson, Public Member
Clarence Hiura, Pharm.D.
John Jones, RPh

Report of March 22, 2006

ACTION

ACTION ITEM 1

That the Board of Pharmacy consider the request from USC School of Pharmacy to amend 16 CCR § 1728 to allow up to 400 additional hours that an intern can earn for pharmacy-related experience outside a pharmacy.

Discussion
Pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its regulations to allow up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship). **(Attachment A)**

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

It was noted that opportunities for pharmacists has expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth year in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. It was anticipated that a large percentage of pharmacy students would still earn the

majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The National Oncology Alliance, Inc. (NOA) spoke in support of the proposal and gave a presentation on opportunities that it has for interns outside a licensed pharmacy and under the supervision of a pharmacist. The intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as it applies to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria and content outline of the California Pharmacy Jurisprudence Examination (CPJE). **(Attachment B)**

Dean Koda-Kimble from the UCSF, School of Pharmacy submitted a letter expressing concern over the proposal and urged the board not to amend the regulation. **(Attachment C)**

The Licensing Committee did not make a recommendation on this proposal. The committee discussed the board's responsibility to protect the public. It is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

ACTION ITEM 2

That the Board of Pharmacy re-approve for 3 years the Accreditation Commission for Health Care, Inc. (ACHC) and Community Health Accreditation Program (CHAP) as accreditation agencies for pharmacies that compound injectable sterile drug products.

Discussion

B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. At that time, ACHC accredited both

home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. Recently ACHC has been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare. **(Attachment D)**

In July 2003, the board approved Community Health Care Accreditation Program (CHAP) as an accreditation agency. CHAPS is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. Currently, one California is CHAP accredited and two pharmacies have applied. There are 63 CHAP accredited pharmacies in 23 states and 16 pharmacies that have applied for accreditation. **(Attachment E)**

Supervising Inspector Dennis Ming reported that the board has not found any compliance issues with either ACHC or CHAP accredited pharmacies

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

1. **Periodic inspection** – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payors** – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

ACTION ITEM 3

That the Board of Pharmacy develop a regulation on the process and criteria to approve accreditation agencies for pharmacies that compound sterile injectable sterile drug products.

Discussion
B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. In July 2003, the board also approved Community Health Care Accreditation Program (CHAP) as an accreditation agency.

Since both agencies have requested that the Board of Pharmacy approve them again as accreditation agencies, and if the approval is granted, it is being recommended that the board pursue a regulation to recognize these agencies in regulation as the Joint Commission on the Accreditation of Healthcare Organizations is recognized in statute.

In addition the regulation would include the application and approval process, the evaluation factors, require the board's self-assessment form for sterile injectable compounding pharmacies as part of the survey process, and that a copy of the survey report be submitted to the board. If the board agrees with this recommendation, proposed language will be drafted.

ACTION ITEM 4

That the Board of Pharmacy extend the waiver to December 31, 2006 to allow a technician to check a technician in the filling of a unit-dose medication system in a hospital inpatient pharmacy for the study "Evaluation of the Impact on Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting" by UCSF School of Pharmacy and Cedars-Sinai Medical Center.

Discussion
Peter Ambrose, Professor of Clinical Pharmacy at UCSF and Rita Shane, Director of Pharmacy Services for Cedars-Sinai Medical Center requested an extension of the waiver for the study by UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting." In April 2004, the Board of Pharmacy granted a two-year waiver for this study. After board approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Center and the Committee on Human Research at UCSF. In order to complete the data collection, analysis and review the results, an extension until December 31, 2006 was requested.

This study was a sequel to the successful experimental program that evaluated pharmacy technicians checking another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy.

The purpose of the sequel study is to evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

Preliminary data from the study was provided to the board at its July meeting and a summary of results from June 21, 2004 – January 1, 2006, is included in this packet. **(Attachment F)**

At its last meeting, the board approved a regulation change to allow a specialized trained pharmacy technician to check another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy that has a clinical program. The proposed regulation change is scheduled for hearing at the April board meeting. If the board approves the proposed regulation, it will take approximately 6-9 months before the regulation would become effective.

NO ACTION

Meeting Summary of March 22, 2006 (Attachment G)

Licensing Statistics (Attachment H)

Competency Committee Report (Attachment I)

Quarterly Status Report on Committee Goals for 2005/06 (Attachment J)

ATTACHMENT A

State of California | Department of Consumer Affairs

Memorandum

To: Licensing Committee | Date: March 9, 2006

From: Patricia Harris
Executive Officer

Subject: Request to increase the number of intern hours that can be earned outside of a pharmacy

At the February meeting, the board was provided with a proposal from a group of pharmacy students representing various schools of pharmacy requesting an increase in the number of intern hours that could be earned outside a pharmacy. Since the proposal was not on the agenda, the board could not take action.

The proposal is now being provided to this committee for consideration. The proposal requests that the board allocate up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. The proposal is attached.

Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship).

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

16 CCR § 1728 states in part:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

DRAFT

RESOLUTION FOR CONSIDERATION BY THE CALIFORNIA STATE BOARD OF PHARMACY

WHEREAS the scope of practice opportunities in the profession of pharmacy has expanded beyond the traditional areas of community and institutional pharmacy, and

WHEREAS the increased scope of pharmacy based opportunities exist for pharmacy school graduates in such areas as the pharmaceutical industry, managed care; regulatory affairs, and other pharmacy-related areas to yet be defined, and

WHEREAS the present existing laws place requirements on both the experience expectations and the quantity of time required of students enrolled in California Schools of Pharmacy in order for them to satisfy both the board exam and licensure standards as stated in the following California statutes and regulations:

> *CA Bus. & Prof. Code, Sec. 4200(a)(5): "The board may license as a pharmacist any applicant who meets the following requirements... Has completed 1,500 hours of pharmacy practice experience or the equivalent in accordance with Sec. 4209."*
>
> *CA Bus. & Prof. Code, Sec. 4209(a)(1)(2): An intern pharmacist shall complete 1,500 hours of pharmacy practice before applying for the pharmacist licensure examination. This pharmacy practice shall comply with the Standards of Curriculum established by the Accreditation Council for Pharmacy Education or with regulations adopted by the board.*
>
> *Title 16, CA Code of Regulations, Sec. 1728(a): ...Applicants shall submit to the board the following: Proof of 1,500 hours of pharmacy practice experience that meets the following requirements:*
> *(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.*
> *(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.*
> *(C) Experience in both community pharmacy and institutional pharmacy practice settings.*
> *(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.* **And**

WHEREAS while the American Council on Pharmaceutical Education (ACPE) does support that the Schools of Pharmacy engage students during the experiential portions of its academic program in various patient care settings, it also encourages other extended boundaries of learning during the experiential portion of the academic program. Under Standard No. 14 (Curricular Core: Pharmacy Practice Experiences), Guideline 14.1 it states the following:

> ***"The scope, intensity, and duration of all of the pharmacy practice experiences should afford students the opportunity to develop skills consistent with expected professional competencies and outcomes. The pharmacy practice experiences should ensure that every student has multiple opportunities to perform pharmaceutical/patient-centered care activities in a variety of settings (including acute care, long-term care, home care, community, ambulatory, administrative)..."*** **And**

WHEREAS all students who undergo the pharmacy curriculum at the University of Southern California School of Pharmacy have multiple pharmacy-related experiences that might include managed care and industrial pharmacy settings that count toward **their 600 required hours of experiential training, those areas of experiences that are more directly patient based are assessed by the use of competency criteria once established by the California State Board of Pharmacy for both community and institutional practices. Students, based upon those competency standards, must achieve a passing mark on each competency stated in order to pass that practice-based course. In passing the practice-based courses, the School is essentially stating that that student is competent to sit for the board examination and practice as a competent pharmacist once the student has passed the board exam, and**

WHEREAS, at this point in time, only a small contingent of those graduating seek positions in the pharmaceutical and managed care industries (perhaps less than 10% of the graduating students), their role in being versed in good patient care principles and standards of care is not diminished based upon the demands of these entities both directly and indirectly being responsible for the assurance that the highest of standards be undertaken that all services and/or products rendered or produced shall be of the highest quality to the recipients of those services and/or products, and

WHEREAS it has not been established, as to at least the knowledge of those who have created this resolution and recommendation, that 1500 hours of patient-related contact is either over or under abundant in assuring that a pharmacist will be minimally competent to practice patient-care pharmacy upon being licensed,

THEREFORE LET IT BE RESOLVED/RECOMMENDED that the California State Board of Pharmacy (Board) recognize that intern experiences in the areas of pharmaceutical industry and managed care can have both a direct and indirect impact on patient care. In so recognizing, be it resolved and recommended that the Board allocate up to 400 hours from the 900 hour remainder that does not include the 600 hours allocated to pharmacy school experiential programming for the purposes of gaining experience in new pharmacy practice related areas such as and not limited to industrial pharmacy and managed care.

THEREFORE LET IT FURTHER BE RESOLVED/RECOMMENDED as a modification of *Title 16, Calif. Code of Regulations, Section 1718[a][1][A-D]* that presently reads as follows:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 900 hours of pharmacy practice experience obtained in a pharmacy.

(B) A maximum of 600 hours of pharmacy practice experience may be granted at the discretion of the board for other experience substantially related to the practice of pharmacy.

(C) Experience in both community pharmacy and institutional pharmacy practice settings.

(D) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

THAT THE MODIFICATION OF *Title 16, Calif. Code of Regulations, Section 1718[a][1][A-D]* BE AS FOLLOWS:

(a) Prior to receiving authorization from the board to take the pharmacist licensure examinations required by section 4200 of the Business and Professions Code, applicants shall submit to the board the following:

(1) Proof of 1500 hours of pharmacy practice experience that meets the following requirements:

(A) A minimum of 500 hours of pharmacy practice experience must be obtained in community and institutional pharmacy practice settings..

(B) A maximum of 1000 hours of pharmacy-related practice experience must be obtained under the supervision of a pharmacist. This 1000 hours may involve, but is not limited to the attainment of pharmacy-related practice experience in a community pharmacy, an institutional pharmacy setting, a managed care organization, and a pharmaceutical industrial setting. The 1000 hours shall include the current 600 hours that is granted for pharmacy school experiential programming, and the additional 400 hours for other pharmacist supervised pharmacy-related experiences.

(C) Pharmacy practice experience that satisfies the requirements for both introductory and advanced pharmacy practice experiences established by the Accreditation Council for Pharmacy Education.

ATTACHMENT B

>
03/14/2006 03:12 PM

Dear Patricia,

Thank you for sending the agenda for the March 22nd meeting. We would like to present during the first agenda item. I will be accompanied by my colleague Kimberly Bardel Whitlock, Pharm.D., also a clinical pharmacist with the National Oncology Alliance.

Please find attached supporting documents for our presentation. We would also like to provide our treatment guideline on larger 11 x 17 paper for ease of use. How many copies do you suggest we bring?

Thank you again, please let me know if there is anything further we need to do in preparation for March 22nd.

Cindy

Cynthia G. Baker, Pharm.D.
Manager, Clinical Services
National Oncology Alliance, Inc.
750 Lindaro St., Suite 350, San Rafael, CA 94901
www.noainc.com
Direct: 415.526.8137 Fax: 415.482.1683
Executive Assistant: Jennifer Boss 415.526.8162
National Oncology Alliance (NOA) provides essential clinical and business information, resources and insight to help transform the practice of oncology.

-----Original Message-----
From: Patricia_Harris@dca.ca.gov
[mailto:Patricia_Harris@dca.ca.gov]
Sent: Friday, March 10, 2006 5:04 PM
To: Cindy Baker
Subject: Licensing Committee Meeting

Attached is the agenda for the March 22nd meeting.

(See attached file: LicComMar06Agenda.doc)

- NOA Rx Intern Job Description 2-2006.doc
- NOA Intern Correlation CPJE Exam Content.doc
- Breast_Guideline_NOA_guideline_v2-1_2005.pdf

Job Description

Position:	**Pharmacist Intern**	**FLSA Status: Exempt – Part Time**
Department:	**Clinical**	**Location: San Rafael**
Reports to:	**Kimberly Bardel Whitlock, Pharm.D.**	**Date: 2/17/2006**
	CA lic. RPH 54164	

Essential Job Functions

Under the guidance of a NOA Clinical Services team member, the intern will be primarily responsible for functions that include the following:

- Prepare clinical summaries of articles in the medical literature, using an established template, for incorporation into the web-based NOA Compare tool
- Use the web-based NOA Compare Clinical Maintenance program to enter, review, or modify content as appropriate as part of quality control
- Collect data about the status of drug FDA approval and Compendial approval as it applies to the NOA Treatment guidelines, and present this information, using an established format, for incorporation into the NOA Compare tool
- Assist team members with other projects such as the NOA Treatment Guidelines or Patient Education Teaching sheets, as directed
- Participate in clinical team meetings to review the status of various projects
- Perform other duties as assigned

Required Skills

Ability to efficiently read and understand scientific literature; familiarity with standard scientific literature citation methods; ability to use computer and the PubMed search engine; familiarity with word processing and spreadsheet software programs, (Word, Excel). Organizational skills and ability to multi-task are essential.

Required Experience and Education

Enrolled in a Doctor of Pharmacy program at accredited School of Pharmacy; valid California Pharmacist Intern license.

National Oncology Alliance, Inc. (NOA)
750 Lindaro Street, Suite 350
San Rafael, CA 94954
(415) 526-8137

NOA Intern Activity Correlation with CPJE Exam Content

Job duties performed by an intern pharmacist employed with the National Oncology Alliance provide experience necessary to prepare for CPJE exam. The table below lists intern duties and the specific correlating exam content.

Please note the CPJE content is pulled directly from the content listed on the California State Board of Pharmacy website, including the same alphabetical and numerical outline format for ease of comparison.

NOA Intern Job Duties	CPJE Exam Content
Assist the clinical team with development and yearly revision of the NOA Treatment Guidelines. These 48 evidence-based guidelines cover cancer and supportive care treatment topics, and include categories of information such as diagnostic workup, tumor staging, initial treatment, adjuvant treatment, recurrent/refractory treatment, and patient monitoring and follow up. Detailed information regarding regimen selection, components, dosing including frequency, duration, and administration are provided. Drug complications (i.e. adverse effects), contraindications, and patient-specific considerations in choosing drug therapy are also addressed in the guidelines.	**Provide Medication to Patients** A. Organize and Evaluate Information 1. Interpret prescription/medication order 2. Obtain information from the patient/ patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 3. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 4. Assess prescription / medication order for completeness, correctness, authenticity, and legality 5. Assess prescription/medication order for appropriateness (e.g. drug selection, dosage, drug interactions, dosage form, delivery system) 6. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments, and/or diagnostic tests 7. Evaluate the pharmaceutical information needs of the patient/patient's representative **Monitor and Manage Patient Outcomes** A. Determine a Course of Action and Manage Patient Outcomes 1. Determine desired therapeutic outcomes 2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary) 3. Determine the need for a referral 4. Communicate the therapeutic plan to the patient/patient's representative, the prescriber and other health care professionals 5. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels) 6. Communicate results of monitoring to

	patient/patient's representative, prescriber and/or other health care professionals 7. Manage drug therapy according to protocols
Assist the clinical team with development and yearly revision of the NOA Patient Education handouts. This library of over 125 handouts follow the Department of Health and Human Services Keystone Guidelines in the provision of information about the uses and benefits, precautions, drug interactions, adverse effects, administration, and storage of chemotherapy and supportive care agents. The library also covers symptom management topics including management of neutropenia, anemia, peripheral neuropathy, nausea and vomiting, sexual dysfunction, sleep disturbance, and others.	**Provide Medication to Patients** A. Organize and Evaluate Information 7. Evaluate the pharmaceutical information needs of the patient/patient's representative B. Dispense Medications 6. Select auxillary labels(s) for container(s). **Monitor and Manage Patient Outcomes** A. Determine a Course of Action and Manage Patient Outcomes 2. Communicate the therapeutic plan to the patient / patient's representative, the prescriber and other health care professionals B. Educate Patients and Health Care Professionals 1. Assess the patient's understanding of the disease and treatment 2. Counsel patient/patient's representative regarding prescription medication 5. Counsel patient/patient's representative regarding non-drug therapy 6. Counsel patient/patient's representative regarding self-monitoring of therapy (e.g., devices, symptoms)
Prepare clinical summaries of studies supporting the use of specific chemotherapy or supportive care treatment regimens. Summaries include a description of study design, study population, inclusion and exclusion parameters, treatment regimen(s), outcomes measures and results, monitoring requirements, reported adverse effects, and statistical analysis. Summaries are generally one page, written for use by oncologists, nurses, and pharmacists.	**Provide Medication to Patients** A. Organize and Evaluate Information 1. Interpret prescription/ medication order 2. Obtain information from the patient/ patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 3. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 4. Assess prescription/medication order for completeness, correctness, authenticity, and legality 5. Assess prescription /medication order for appropriateness (e.g. drug selection, dosage, drug interactions, dosage form, delivery system) 6. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments, and/or diagnostic tests 7. Evaluate the pharmaceutical information needs of the patient/patient's representative **Monitor and Manage Patient Outcomes** A. Determine a Course of Action and Manage Patient

	Outcomes 1. Determine desired therapeutic outcomes 2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary) 3. Determine the need for a referral 4. Communicate the therapeutic plan to the patient/patient's representative, the prescriber and other health care professionals 5. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels) 6. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals 7. Manage drug therapy according to protocols
Enter, review, or modify content in the web-based NOA Compare clinical and cost/reimbursement analysis tool with the guidance of the clinical staff. Information the intern will enter/review/modify includes drug therapy regimen components, dosing, administration (including associated premedications, vehicles, and antiemetics), reported adverse effects, and recommended monitoring parameters[CB1][CB2] (e.g. laboratory tests).	**Provide Medication to Patients** A. Organize and Evaluate Information 1. Interpret prescription/medication order 2. Obtain information from the patient/ patient's representative for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 3. Obtain information from prescriber and/or health care professionals for patient profile (diagnosis or desired therapeutic outcome, allergies, adverse reactions, medical history, etc.) 4. Assess prescription / medication order for completeness, correctness, authenticity, and legality 5. Assess prescription /medication order for appropriateness (e.g. drug selection, dosage, drug interactions, dosage form, delivery system) 6. Evaluate the medical record/patient profile for any or all of the following: disease states, clinical condition, medication use, allergies, adverse reactions, disabilities, medical/surgical therapies, laboratory findings, physical assessments, and/or diagnostic tests 7. Evaluate the pharmaceutical information needs of the patient/patient's representative **Monitor and Manage Patient Outcomes** A. Determine a Course of Action and Manage Patient Outcomes 1. Determine desired therapeutic outcomes 2. Develop a therapeutic regimen for prescription medications (e.g., recommend alteration of prescribed drug regimen; select drug if necessary) 3. Determine the need for a referral 4. Communicate the therapeutic plan to the patient/patient's representative, the prescriber and other health care professionals 5. Recommend/order necessary monitoring and screening procedures (e.g., blood pressure, glucose levels, drug levels)

	6. Communicate results of monitoring to patient/patient's representative, prescriber and/or other health care professionals 7. Manage drug therapy according to protocols

BREAST CANCER, FEMALE HIGH-RISK ASSESSMENT

Diagnostic Work-Up

High-Risk Breast Assessment

- Mammogram
- Obtain family history and assess the need for and the appropriateness of genetic counseling/testing.
- Assess patient for overall risk according to the Gail Model for Risk Assessment. Risk factors include the following. Refer to the NCI website for further information.
  - current age
  - age at menarche
  - age at first live birth
  - number of previous breast biopsies
  - presence of atypical hyperplasia
  - number of first degree relatives
- History and physical exam

Emerging Issues:

- Nipple aspirate and ductal lavage for purposes of risk stratification ***remain investigational at this time***
- MRI ***breast screening*** may be used in very high risk patients such as BRCA- 1 and -2 mutation carriers ***and women with very dense breasts*** as small studies have shown it to be more sensitive than mammography.

Staging

High-Risk Breast Assessment

No diagnosis of cancer but strong family history or BRCA-1/ BRCA-2 positive

Risk Reduction Intervention

High-Risk Breast Assessment

For patients with BRCA -1 and/or – 2 mutations consider:

- Lifestyle modification
- Tamoxifen 20 mg PO QD x 5 years after discussion of pros and cons
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Initial Treatment

High-Risk Breast Assessment

- Appropriate genetic testing and counseling
- Discuss pros and cons of prophylactic mastectomy and/or prophylactic oophorectomy
- Clinical trials in cancer prevention - Please refer to the following website: http://cancertrials.nci.nih.gov/

Adjuvant Treatment

High-Risk Breast Assessment

Not Applicable

First and Subsequent Recurrent/Refractory Treatment

High-Risk Breast Assessment

Not Applicable

Monitoring/Follow-Up

High-Risk Breast Assessment

- History & physical exam every 6-12 months
- Annual mammogram if prophylactic mastectomy not chosen
- Monitor for ovarian cancer if prophylactic oophorectomy not chosen. This typically includes the following every 6-12 months:
  - Transvaginal ultrasound
  - CA-125

Emerging Issue

MRI breast screening may be used in very high risk patients such as BRCA- 1 and -2 mutation carriers and women with very dense breasts as small studies have shown it to be more sensitive than mammography. Some clinicians may do this procedure annually or may alternate every 6 – 12 months the MRI with the mammogram.

Expert Panel:
Debu Tripathy, MD: Director, Komen Center for Breast Cancer Research University of Texas Southwestern Medical Center at Dallas
Marilyn Leitch, MD: University of Texas Southwestern Medical Center at Dallas
Linda Bosserman, MD Wilshire Oncology Medical Group in Rancho Cucamonga, CA

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BREAST CANCER, FEMALE Stage 0

Diagnostic Work-Up

Stage 0: LCIS
To make the diagnosis obtain the following:
- bilateral mammography
- biopsy of ***lesion*** (core, incisional or excisional)

Initial work up consists of the following:
- Review pathology results
- Obtain family history and assess the need for and the appropriateness of genetic counseling/testing
- Assess patient for overall risk according to the Gail Model for Risk Assessment. Risk factors include the following. Refer to the NCI website for further information.
  - current age
  - age at menarche
  - age at first live birth
  - number of previous breast biopsies
  - presence of atypical hyperplasia
  - number of first degree relatives
- History and physical exam

Emerging Issues:
- Nipple aspirate and ductal lavage for purposes of risk stratification ***remain investigational at this time***

Stage 0: DCIS
To make the diagnosis obtain the following:
- bilateral mammography
- biopsy of ***lesion*** (core, incisional or excisional)

Initial work up consists of the following:
- Review pathology results
- Obtain family history and assess the need for and the appropriateness of genetic counseling/testing
- Assess patient for overall risk according to the Gail Model for Risk Assessment. Risk factors include the following. Refer to the NCI website for further information.
  - current age
  - age at menarche
  - age at first live birth
  - number of previous breast biopsies
  - presence of atypical hyperplasia
  - number of first degree relatives
- History and physical exam

Staging

Stage 0: LCIS -
5yr survival: 98%

Tis, N0, M0
(25% chance of developing an invasive cancer in either breast within 25 years)

Tis: Carcinoma in situ; intraductal carcinoma, lobular carcinoma in situ, or Paget's disease of the nipple with no associated tumor mass
N0: No regional lymph node metastasis
M0; No distant metastasis

Stage 0-DCIS :
5yr survival: 98%

Tis, N0, M0

Tis: Carcinoma in situ; intraductal carcinoma, lobular carcinoma in situ, or Paget's disease of the nipple with no associated tumor mass
N0: No regional lymph node metastasis
M0: No distant metastasis

Risk Reduction Intervention

Stage 0: LCIS :
- Consider lifestyle modification
- Consider tamoxifen 20 mg PO QD x 5 years after discussion of pros and cons
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Stage 0-DCIS
- Consider lifestyle modification
- Consider Tamoxifen 20 mg PO QD x 5 years after discussion of pros and cons
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Initial Treatment

Stage 0: LCIS
Patients may be considered for:
- Close surveillance is strongly recommended
- Bilateral simple mastectomy/reconstruction (consider in women with a strong family history)
- Clinical trials in cancer prevention - Please refer to the following website: http://cancertrials.nci.nih.gov/

Stage 0 - DCIS
Patients may be considered for mastectomy or wide excision. The treatment choice depends upon tumor characteristics and the patient's desire for breast preservation. The survival benefit is equivalent for the following options if the DCIS can be completely resected:
- Excision alone with wide negative margins ***(ideally ≥ 1cm)*** for small, low grade tumors
- ***Specimen radiographs should be done to ensure removal of density and/or calcifications***
- Excision with negative margins plus radiation for high grade tumors
- Simple mastectomy which may be followed by immediate or delayed reconstruction
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Notes:
- Axillary node dissection is generally not indicated for DCIS
- ***When a mastectomy is done, SLND should be strongly considered as invasive disease may be found in the mastectomy final pathology exam. If the breast has been removed, SLND cannot be performed and ALND would be required for axillary staging.***
- ***If breast conserving surgery is performed for high risk DCIS, SLND may be done.***

Note: After excision of mammographically detected DCIS ***with microcalcifications***, obtain a follow-up mammogram if breast preservation chosen.

Adjuvant Treatment

Stage 0: LCIS
None

Stage 0 - DCIS
- Radiation depending on grade, size and margins
- Tamoxifen 20 mg PO QD x 5 years in ***hormone-receptor positive*** patients who have undergone breast conserving surgery ***and radiation***
- ***The efficacy of tamoxifen without radiation in preventing local recurrence has not been established***

First and Subsequent Recurrent/Refractory Treatment

Stage 0: LCIS
If patient develops local or invasive disease, restage and treat according to stage.

Stage 0 - DCIS
The options for recurrent disease therapy include:
- Re-excision followed by radiation (if no prior radiation)
- Simple mastectomy which may be followed by immediate or delayed reconstruction
- If patient has invasive disease, restage and treat according to stage

Monitoring/Follow-Up

Stage 0: LCIS
- History & physical exam every 6 – 12 months
- Annual mammogram
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding.

Stage 0 - DCIS
- History & Physical Exam every 6 months
- Mammography every 6 months x 1 year then annually thereafter
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding.

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BREAST CANCER, FEMALE Stage I

Diagnostic Work-up

Stage I:
To Make the Diagnosis:
- bilateral mammography
- biopsy of *lesion* (core, incisional or excisional)

Initial Work-up Consists of the Following:
- History and physical exam
- CBC, Plts & Diff., Chemistry panel
- Chest X-ray if clinically indicated
- Review pathology results
- Scans as clinically indicated
- ***Baseline*** MUGA scan or Echo if clinically indicated for patients receiving anthracycline or trastuzumab
- Evaluate the following prognostic factors:
  - tumor size and grade
  - lymph node involvement
  - age/ menopausal status
  - ER/PR status
  - S-phase may be used to assist in decision making
  - ***HER-2/neu status should be obtained for future use if patient were to relapse but remains controversial for guidance in decision making for early-stage disease***

Note: The likelihood of metastatic disease detected by radiographic means in an asymptomatic individual needs to be weighed against the chance of a false positive and the evaluation that would ensue. Routine bone scans in patients with stage I/II disease could be reserved for those with musculoskeletal symptoms or elevated alkaline phosphatase.

Emerging Issues:
- At this time, the optimal method of testing HER 2/neu over expression (immunohistochemistry vs. FISH) remains undefined. Some experts agree that if HER- 2/neu by immuno-histochemistry is 0, 1+, or 3+, the results are reliable. However, if 2+, they recommend sending for FISH. Testing should be performed at experienced testing centers.
- A new 21-gene assay has shown a high degree of accuracy in predicting recurrence risk ***and benefit from chemotherapy*** in patients with node-negative, ER+ breast cancer, however, more validation is in progress. To date, the use of these assays has not been demonstrated to lead to a better outcome than conventional staging and grading.

Staging

Stage I :
5yr survival : 90%
T1, N0, M0

Initial Treatment

Stage I:
- Treatment approach depends upon tumor characteristics, breast size and patient's desire to preserve the breast. ***Assessment of axillary lymph node status for clinically node negative patients is recommended by way of a sentinel lymph node dissection. If SLND is unavailable, an axillary lymph node dissection may be done***

  Note: Quality standards for sentinel lymph node dissection have been set by the ACOSOG and ASBS. Standards include 30 cases where sentinel lymph node has been identified followed by complete dissection with 85% sentinel lymph node identification with 95% specificity.

- For patients in whom chemotherapy is not a consideration (e.g. elderly patientswith very favorable tumors), the elimination of axillary lymph node dissection may be considered.

The survival benefit is equivalent for the following 2 options:
- Lumpectomy followed by ***whole breast*** radiation. Following excision, the margins should be evaluated.
  - If positive margins are observed, a more extensive excision should be performed.
  - If negative margins are not possible, a mastectomy should be performed.
- Modified radical mastectomy or simple mastectomy which may be followed by immediate or delayed reconstruction. Patients with positive margins should receive chest wall radiation.

Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Emerging Issues:
Partial breast radiation is being done. Studies to date have reported low recurrence rates in patients at low risk for local recurrence. A prospective trial is currently underway which may help define the risks and benefits of this approach.

Adjuvant Treatment

Stage I:
All tumors < 1 cm independent of other factors:
(Note: there have not been adequately sized studies in this population of patients to support specific evidence-based treatment recommendations)
- No Treatment
- Follow treatment recommendations below based upon hormone receptor status, menopausal status, and other patient specific factors

Hormone receptor positive, pre- menopausal (tumors > 1cm):
There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially.

Lower←Chemo *Intensive*→Higher

Chemotherapy†‡	Hormonal Therapy
• None	• Tamoxifen x 5 years. ***When patients become menopausal, an aromatase inhibitor should be added for 5 years.*** • LHRH Agonist (Goserelin, Leuprolide) • Oophorectomy ***Note: In women who are recently rendered post-menopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles or ***8 cycles depending on regimen used*** • AC x 4 cycles	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor positive, postmenopausal (tumor >1cm)
There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially and not concurrently

Lower←Chemo *Intensive*→Higher

Chemotherapy†‡	Hormonal Therapy
• None	• ***Aromatase inhibitor (AI) x 5 years*** • ***Tamoxifen x 2 yrs followed by an AI x 3 yrs*** • ***Tamoxifen x 5 years*** • Tamoxifen x 5 yrs followed by an AI x 5 yrs Note: No benefit has been seen with continuation of tamoxifen longer than 5 yrs. ***The overall survival*** benefit of using an AI instead of or following tamoxifen ***has not yet been demonstrated.*** The use of an AI in place of or after 2 yrs. of tamoxifen has ***demonstrated a significant benefit on recurrence-free survival during the first 10 years after diagnosis.*** ***Note: In women who are recently rendered post-menopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles or ***8 cycles depending on regimen used*** • AC x 4 cycles	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor negative, pre- and postmenopausal (tumor > 1cm) – ***high risk node negative disease***
Hormone therapy in this group of patients is not appropriate. Choose a treatment option from the chemotherapy column.

Lower←Chemo *Intensive*→Higher

Chemotherapy†‡	Hormonal Therapy
• None	• None
• CMF x 6 cycles or ***8 cycles depending on regimen used*** • AC x 4 cycles	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

† The more ***intensive*** chemotherapy regimens are accompanied by greater toxicity and cost and must be balanced by the patient's overall risk and absolute benefit. Higher risk tumors based on size, grade, lymphovascular invasion and other aggregated characteristics may warrant more aggressive chemotherapy regimens.
‡ There are inadequate data to draw conclusions about the benefit of chemotherapy in women > 70 yrs. For all other age groups there is evidence of benefit. Benefit from chemotherapy is greater in younger women and steadily decreases with age.

Emerging Issues:
- Choosing an AI over tamoxifen based on HER-2/neu protein overexpression is currently under study and should not affect treatment decisions at this time.

Monitoring/Follow-Up

Stage I
- History/Physical Exam
  - every 6 months years 1-3 after primary therapy, then every 6-12 months years 4-5, then annually thereafter
- Follow-up of the patient should be coordinated and not duplicated. Continuity of care should be conducted by a physician experienced in the surveillance of cancer patients.
- Annual mammogram
- Blood work, chest X-ray and scans if clinically indicated
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding.
- Patients receiving an aromatase inhibitor should have periodic monitoring of bone mineral density. Anti-resorptive therapy (preferable a non-SERM) should be considered if bone mineral density is depressed ***and all patients should take calcium and vitamin D***
- The use of serum markers for following response in patients with recurrent disease should be restricted to patients in whom other objective measures are equivocal
- ***In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
- ***Patients with BRCA-1 and 2 mutations that have not elected to undergo contralateral prophylactic mastectomy, consider annual MRI screening***
- ***Patients receiving trastuzumab should have cardiac monitoring at 3, 6, and 12 months after beginning trastuzumab therapy. Trastuzumab therapy should be withheld for the following:***
  - ***If ejection fraction drops more than 10% below the institutional normal***
  - ***If the EF drops more than 15% overall***
  - ***Clinical CHF with a documented drop in EF***
  - ***If EF normalizes within 4 weeks may consider resuming trastuzumab therapy***

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BREAST CANCER, FEMALE Stage II-IIIA

Diagnostic Work-Up

Stage II – IIIA
To make the diagnosis:
- bilateral mammography
- biopsy of *lesion* (core, incisional or excisional)

Initial Work-up consists of the following:
- History and physical exam
- CBC, Plts & Diff., Chem panel
- Chest X-ray if clinically indicated
- Review pathology results
- Scans as clinically indicated
- *Baseline* MUGA scan or Echo if clinically indicated for patients receiving anthracycline or herceptin
- Evaluate the following prognostic factors:
  - tumor size and grade
  - S-phase may be used to assist in decision making
  - ER/PR levels
  - lymph node involvement
  - menopausal status
  - ***HER-2/neu status should be obtained for future use if patient were to relapse but remains controversial for guidance in decision making for early-stage disease***

Note: The likelihood of metastatic disease detected by radiographic means in an asymptomatic individual needs to be weighed against the chance of a false positive and the evaluation that would ensue. Routine bone scans in patients with stage I/II disease could be reserved for those with musculoskeletal symptoms or elevated alkaline phosphatase.

Emerging Issues:
At this time, the optimal method of testing HER 2/neu over-expression (immunohistochemistry vs. FISH) remains undefined. Some experts agree that if HER-2/neu by immunohistochemistry is 0, 1+, or 3+, the results are reliable. However, if 2+, they recommend sending for FISH. Testing should be performed at experienced testing centers.

Staging

Stage II - III:
5yr survival: 75%
Stage IIA
T0, N1, M0
T1, N1, M0
T2, N0, M0

Stage IIB
T2, N1, M0
T3, N0, M0

Initial Treatment

Stage II-IIIA
Treatment approach depends upon tumor characteristics, breast size and patient's desire to preserve the breast. ***Assessment of axillary lymph node status for clinically node negative patients is recommended by way of a sentinel lymph node dissection. If SLND is unavailable, an axillary lymph node dissection may be done..***

- Neoadjuvant chemotherapy may be considered for patients who would benefit from cytoreduction and in whom chemotherapy will be part of their treatment regimen. Patients should continue to receive chemotherapy until the complete neoadjuvant regimen is given, until response plateau achieved, or until progression. If the patient progresses during chemotherapy, change the regimen, perform a modified radical mastectomy, or breast conserving surgery, if feasible. The objective response to chemotherapy should be assessed with each cycle. Regimens which may be considered for neoadjuvant administration include:
  - Anthracycline-based regimen (AC, FAC, CAF, FEC, CEF) or AC followed by a taxane.
    - ***HER2 positive patients may be considered for anthracycline-based therapy followed by a combination of trastuzumab plus paclitaxel***
  - ***Docetaxel – Capecitabine***
  - ***Doxorubicin – Paclitaxel***
  - CMF
  - Tamoxifen alone can be considered in post-menopausal hormone receptor positive women and should be added after chemotherapy for pre-menopausal woman.
    - If tumor ***reduction is not suitable for breast conserving surgery***, consider modified radical mastectomy and axillary node dissection if SLND not done followed by external beam radiation to the breast and nodal regions. The use of SLND following neoadjuvant chemotherapy can be considered.
    - If tumor size is significantly decreased, consider conservative treatment (e.g., quadrantectomy) and axillary node dissection (if SLND not done) followed by external beam radiation to the breast and nodal region. The use of SLND following neoadjuvant chemotherapy can be considered.
- Lumpectomy followed by radiation if tumor is ≤ 5 cm. Following excision, the margins should be evaluated.
  - If positive margins are observed, a more extensive excision should be performed.
  - If negative margins are not possible, a mastectomy should be performed.
- Modified radical mastectomy or simple mastectomy (in women with a negative SLND or in those who have already had an axillary lymph node dissection) which may be followed by immediate or delayed reconstruction.
  - Patients with positive margins or who have ≥ 4 positive lymph nodes should receive radiation to the chest wall and draining lymph nodes.
  - Consider radiation for Stage II, T_3 tumors.
  - Radiotherapy may be considered for patients with 1-3 positive nodes particularly if unfavorable tumor characteristics.
  - Radiation generally follows chemotherapy.
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Emerging Issues:
The use of trastuzumab in the neoadjuvant setting for HER-2/neu positive operable breast cancer was associated with a higher pathological complete response rate in one small randomized trial, but has not yet been shown to improve long-term outcome, hence this remains investigational.

Adjuvant Treatment

Stage II – IIIA
- All patients who have not received neoadjuvant therapy should receive adjuvant systemic therapy. For patients who have received neoadjuvant chemotherapy, additional chemotherapy after surgery may be considered. Patients with > 10 positive nodes are considered high-risk for relapse. Anthracycline-based chemotherapy for 6 cycles or a taxane containing regimen is the preferred adjuvant therapy.
- ***For patients that are HER2 positive who have already completed adjuvant chemotherapy, consideration can be given to administering a year of trastuzumab therapy***

Hormone receptor positive, premenopausal (tumors > 1cm):
There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially.

Lower—Chemo Intensive—Higher

Chemotherapy †‡	Hormonal Therapy
• None	• Tamoxifen x 5 years. ***When patients become menopausal, an aromatase inhibitor should be added for 5 years*** • LHRH Agonist (Goserelin, Leuprolide) • Oophorectomy ***Note: In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles • ***Epirubicin – tamoxifen (elderly)***	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC-100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor positive, postmenopausal (tumor >1cm)
There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially and not concurrently.

Lower—Chemo Intensive—Higher

Chemotherapy†‡	Hormonal Therapy
• None	• ***Aromatase inhibitor (AI) x 5 years*** • ***Tamoxifen x 2 yrs followed by an AI x 3 yrs*** • ***Tamoxifen x 5 years*** • Tamoxifen x 5 yrs followed by an AI x 5 yrs Note: No benefit has been seen with continuation of tamoxifen longer than 5 yrs. ***The overall survival*** benefit of using an AI instead of or following tamoxifen ***has not yet been demonstrated.*** The use of an AI in place of or after 2 yrs. of tamoxifen has ***demonstrated a significant benefit on recurrence-free survival during the first 10 years after diagnosis.*** ***In women who are recently rendered post-menopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles • ***Epirubicin – tamoxifen (elderly)***	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC-100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor negative, pre- and postmenopausal (tumor > 1cm)
Hormone therapy in this group of patients is not appropriate. Choose a treatment option from the chemotherapy column.

Lower—Chemo Intensive—Higher

Chemotherapy†‡	Hormonal Therapy
• None	• None
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC-100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

† The more aggressive chemotherapy regimens are accompanied by greater toxicity and cost and must be balanced by the patient's overall risk and absolute benefit.. Higher risk tumors based on size, grade, lymphovascular invasion and other aggregated characteristics may warrant more aggressive chemotherapy regimens.
‡ There are inadequate data to draw conclusions about the benefit of chemotherapy in women > 70 yrs. For all other age groups there is evidence of benefit. Benefit from chemotherapy is greater in younger women and steadily decreases with age.

Emerging Issues:
- Choosing an AI over tamoxifen based on HER-2/neu protein overexpression is currently under study and should not affect treatment decisions at this time.

Monitoring/Follow-Up

Stage II-IIIA
- History/Physical Exam
  - every 3-6 months years 1-3 after primary therapy, then every 6-12 months years 4-5, then annually thereafter
- Follow-up of the patient should be coordinated and not duplicated. Continuity of care should be conducted by a physician experienced in the surveillance of cancer patients.
- Annual mammogram
- Blood work, chest X-ray and scans if clinically indicated.
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding.
- Patients receiving an aromatase inhibitor should have periodic monitoring of bone mineral density. Anti-resorptive therapy (preferably a non-SERM) should be considered if bone mineral density is depressed. ***and all patients should take calcium and vitamin D***
- The use of serum markers for following response in patients with recurrent disease should be restricted to patients in whom other objective measures are equivocal.
- ***In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
- ***Patients with BRCA-1 and 2 mutations that have not elected to undergo contralateral prophylactic mastectomy, consider annual MRI screening***
- ***Patients receiving trastuzumab should have cardiac monitoring at 3, 6, and 12 months after beginning trastuzumab therapy. Trastuzumab therapy should be withheld for the following:***
  - ***If ejection fraction drops more than 10% below the institutional normal***
  - ***If the EF drops more than 15% overall***
  - ***Clinical CHF with a documented drop in EF***
  - ***If EF normalizes within 4 weeks may consider resuming trastuzumab therapy***

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BREAST CANCER, FEMALE Stage IIIB/IIIC

Diagnostic Work-up

Stage IIIB/IIIC

To make the diagnosis:

- bilateral mammography
- biopsy of *lesion* (core, incisional or excisional)
- Skin biopsy may be needed to confirm inflammatory cancer if clinical features are equivocal and pathology *shows* tumor cells in intradermal lymphatics.

Initial Work-up Consists of the following:

- History and physical exam
- CBC, Plts & Diff., Chem panel
- Review pathology results
- Bone scan
- CXR
- Additional scans as clinically indicated (such as an abdominal CT scan if LFT's are elevated).
- ***Baseline*** MUGA scan or Echo if clinically indicated for patients receiving anthracycline or trastuzumab
- Evaluate the following prognostic factors:
  - tumor size and grade
  - S-phase may be used to assist in decision making
  - ER/PR levels
  - lymph node involvement
  - menopausal status
  - ***HER-2/neu status should be obtained for future use if patient were to relapse but remains controversial for guidance in decision making for early-stage disease***

Emerging Issues:

At this time, the optimal method of testing HER 2/neu over-expression (immunohistochemistry vs. FISH) remains undefined. Some experts agree that if HER- 2/neu by immunohistochemistry is 0, 1+, or 3+, the results are reliable. However, if 2+, they recommend sending for FISH. Testing should be performed at experienced testing centers.

Staging

Stage IIIB-IIIC

(inoperable at time of diagnosis)

T4, N0, M0
T4, N1, M0
T4, N2, M0

(includes inflammatory breast cancer)

Stage IIIC

Any T, N3, M0

Initial Treatment

Stage IIIB-IIIC

- Neoadjuvant chemotherapy may be used to attempt and shrink the tumor so that it will be amenable to resection in patients who are inoperable at the time of presentation. Patients should continue to receive chemotherapy until the complete neoadjuvant regimen has been given, until response plateau achieved or until progression. If the patient progresses during chemotherapy, change systemic therapy or perform a modified radical mastectomy. The objective response to chemotherapy should be assessed with each cycle. Regimens that may be considered include:
  - Anthracycline-based regimen (eg, FAC, CAF, FEC, or CEF) or AC followed by a taxane.
    - ***HER2 positive patients may be considered for anthracycline-based therapy followed by a combination of trastuzumab plus paclitaxel***
  - ***Docetaxel – Capecitabine***
  - ***Doxorubicin – Paclitaxel***
  - CMF
  - Tamoxifen alone can be considered in postmenopausal hormone receptor positive women and should be added after chemotherapy for premenopausal women.
    - If tumor ***reduction is not suitable for breast conserving surgery***, consider modified radical mastectomy and axillary node dissection followed by external beam radiation to the chest wall and nodal regions.
    - If tumor size is significantly decreased, consider conservative treatment (e.g., quadrantectomy) and axillary node dissection followed by external beam radiation to the breast and nodal region.
    - If neoadjuvant chemotherapy succeeds in debulking an inoperable tumor, surgical resection should be attempted.
- Patients may be considered for modified radical mastectomy initially, followed by chemotherapy and radiation.
- ***Sentinel node biopsy can be considered for patients with clinically negative nodes either pre or post chemotherapy, although the false negative rate in this setting has not been firmly established***
- Patients with N3 disease should be considered for surgical resection and/or radiation therapy to the supraclavicular lymph nodes.
- For patients who are not surgical candidates initially, the same chemotherapy regimens which would be used in the first recurrent/refractory treatment setting may be considered.
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Adjuvant Treatment

Stage IIIB-IIIC

All patients who have not received neoadjuvant therapy should receive adjuvant systemic therapy. For patients who have received neoadjuvant chemotherapy, additional chemo-therapy after surgery may be considered. Patients with > 10 positive nodes are considered high-risk for relapse. Anthracycline-based chemotherapy for 6 cycles or a taxane containing regimen is the preferred adjuvant therapy.

For patients that are HER2 positive who have already completed adjuvant chemotherapy, consideration can be given to administering a year of trastuzumab therapy

Hormone receptor positive, pre- menopausal (tumors > 1cm):

There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially.

Lower←Chemo *Intensive*→higher

Chemotherapy†‡	Hormonal Therapy
• None	• Tamoxifen x 5 years. ***When patients become menopausal, an aromatase inhibitor should be added for 5 years*** • LHRH Agonist (Goserelin, Leuprolide) • Oophorectomy ***In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles • ***Epirubicin – tamoxifen (elderly)***	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC-100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor positive, postmenopausal (tumor >1cm)

There are multiple different ways in which hormonal therapy and chemotherapy may be combined. Treatment options include combining 1 or more selections from the hormone column with 1 selection from the chemotherapy column. When chemotherapy and hormonal therapy are both used they should be given sequentially and not concurrently.

Lower←Chemo *Intensive*→higher

Chemotherapy†‡	Hormonal Therapy
• None	• ***Aromatase inhibitor (AI) x 5 years*** • ***Tamoxifen x 2 yrs followed by an AI x 3 yrs*** • ***Tamoxifen x 5 years*** • Tamoxifen x 5 yrs followed by an AI x 5 yrs Note: No benefit has been seen with continuation of tamoxifen longer than 5 yrs. ***The overall survival*** benefit of using an AI instead of or following tamoxifen ***has not yet been demonstrated.*** The use of an AI in place of or after 2 yrs. of tamoxifen has ***demonstrated a significant benefit on recurrence-free survival during the first 10 years after diagnosis.*** ***In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles • ***Epirubicin – tamoxifen (elderly)***	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC – 100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

Hormone Receptor negative, pre- and postmenopausal (tumor > 1cm)

Hormone therapy in this group of patients is not appropriate. Choose a treatment option from the chemotherapy column.

Lower←Chemo *Intensive*→higher

Chemotherapy †‡	Hormonal Therapy
• None	• None
• CMF x 6 cycles ***or 8 cycles depending on regimen used*** • AC x 4 cycles	
• CAF/FAC x 6 cycles • FEC/CEF x 6 cycles • AC → Paclitaxel or Docetaxel • ***FEC-100 x 3 → Docetaxel x 3*** • ***AC → Paclitaxel + Trastuzumab (for HER2 + patients only)***	
• Dose Dense AC → Paclitaxel • TAC	

† The more aggressive chemotherapy regimens are accompanied by greater toxicity and cost and must be balanced by the patient's overall risk and absolute benefit.. Higher risk tumors based on size, grade, lymphovascular invasion and other aggregated characteristics may warrant more aggressive chemotherapy regimens.

‡ There are inadequate data to draw conclusions about the benefit of chemotherapy in women > 70 yrs. For all other age groups there is evidence of benefit. Benefit from chemotherapy is greater in younger women and steadily decreases with age.

Emerging Issues:

- Choosing an AI over tamoxifen based on HER-2/neu protein overexpression is currently under study and should not affect treatment decisions at this time.

Monitoring/Follow-Up

Stage IIIB-IIIC:

- History/Physical Exam
  - every 3-6 months years 1-3 after primary therapy, then every 6-12 months years 4-5, then annually thereafter
- Follow-up of the patient should be coordinated and not duplicated. Continuity of care should be conducted by a physician experienced in the surveillance of cancer patients.
- Annual mammogram
- Blood work, chest X-ray and scans if clinically indicated.
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding.
- Patients receiving an aromatase inhibitor should have periodic monitoring of bone mineral density. Anti-resorptive therapy (preferable a non-SERM) should be considered if bone mineral density is depressed ***and all patients should take calcium and vitamin D***
- The use of serum markers for following response in patients with recurrent disease should be restricted to patients in whom other objective measures are equivocal.
- ***In women who are recently rendered postmenopausal, ovarian estrogen production may persist therefore estradiol levels with high sensitivity assay should be done to confirm menopausal status. A level of < 10 picograms/dL should be observed.***
- ***Patients with BRCA-1 and 2 mutations that have not elected to undergo contralateral prophylactic mastectomy, consider annual MRI screening***
- ***Patients receiving trastuzumab should have cardiac monitoring at 3, 6, and 12 months after beginning trastuzumab therapy. Trastuzumab therapy should be withheld for the following:***
  - ***If ejection fraction drops more than 10% below the institutional normal***
  - ***If the EF drops more than 15% overall***
  - ***Clinical CHF with a documented drop in EF***
  - ***If EF normalizes within 4 weeks may consider resuming trastuzumab therapy***

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Treatment of First Recurrence (Stages I – IIIC)

Local recurrence:

- Patients who experience local recurrence after lumpectomy and radiation should undergo a mastectomy. Reconsider additional systemic therapy based upon the characteristics of the recurrence and history of previous treatment.
- ***Patients who experience local recurrence after a mastectomy should be surgically resected if amenable and should receive radiation to the chest wall and lymph nodes. Consider additional systemic therapy. Note: No prospective data exists regarding which patients should receive additional therapy; the decision to treat should be on a case by case basis. Post-menopausal patients who were initially on tamoxifen or no hormonal therapy with ER/PR+ tumors should be placed on an aromatase inhibitor for 5 years***

Isolated Metastatic Recurrences

- ***Single isolated cranial or pulmonary metastases should be considered for surgical resection or radiosurgery [note: radiosurgery does not apply to pulmonary lesions]***
- ***Most patients with brain metastases should receive radiation therapy***
- ***Patients with spinal cord compression should receive palliative radiation. Surgical decompression may be considered for selected cases***
- ***Patients with an isolated bone metastasis may be considered for palliative radiation therapy only.***
- ***May consider intrathecal liposomal Ara-C (DepoCyt), intrathecal MTX, appropriate***
- ***Systemic chemotherapy or palliative radiation for patients with meningeal disease.***

Metastatic recurrence:

Note: Patients with metastatic breast cancer should have their HER-2/neu status assessed if it was not done at the time of primary diagnosis. The current FDA recommendation is to treat patients who are 2+ or 3+ with trastuzumab. See "Emerging Issues" regarding 2+ HER-2/neu protein overexpression.

Hormone receptor positive, and bone/soft tissue recurrence only:

- For patients who have had prior anti-estrogen within the past year, strong consideration should be given to additional 2nd line hormonal therapy.
- For patients who have had no prior anti-estrogen or who are more than 1 year off of an anti-estrogen:
  - If pre-menopausal: Tamoxifen, an LHRH Agonist, an oophorectomy or combination of some
  - If post-menopausal: tamoxifen, toremifene, or an AI (depending on previous treatment)
- Clinical trials- Refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov

Hormone receptor positive with symptomatic visceral disease:

- Patients with extensive visceral or immediate life-threatening disease might be optimally treated with initial chemotherapy and then considered for maintenance treatment with hormone therapy. Treatment choices include one of the following:

  Combination Therapy
  - Anthracycline-based therapy (AC, FAC, CAF, FEC, CEF, EC)
  - Doxorubicin – taxane (doxorubicin – paclitaxel or doxorubicin – docetaxel)
  - ***Capecitabine – taxane (docetaxel or paclitaxel)***
  - ***Gemcitabine – Paclitaxel***
  - CMF
  - ***Carboplatin – Paclitaxel (randomized trials have not been performed with this combination)***

  Single Agent Therapy (***numerous combinations of the following agents have been studied in phase II trials. Many have shown efficacy but none have shown benefit over single agent therapy.***)
  - Single-agent taxane therapy – Gemcitabine – Vinorelbine
  - Single-agent anthracycline therapy – Infusional 5FU – ***nab – paclitaxel (Abraxane)***
  - Capecitabine – liposomal doxorubicin
- Clinical trials- Refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov

Hormone receptor negative, pre- and postmenopausal patients:

- For patients who recur following adjuvant chemotherapy, the treatment will depend on a number of factors, including time of recurrence, previous therapy, patient symptoms, PS, and other patient specific considerations. Treatment can include combination or single-agent chemotherapy.

  Combination Therapy
  - Anthracycline-based therapy (AC, FAC, CAF, FEC, CEF, EC)
  - Doxorubicin – taxane (doxorubicin – paclitaxel or doxorubicin – docetaxel)
  - ***Capecitabine – taxane (docetaxel or paclitaxel)***
  - ***Gemcitabine – Paclitaxel***
  - CMF
  - ***Bevacizumab – Paclitaxel***
  - ***Carboplatin – Paclitaxel (randomized trials have not been performed with this combination)***

  Single Agent Therapy (***numerous combinations of the following agents have been studied in phase II trials. Many have shown efficacy but none have shown benefit over single agent therapy.***)
  - Single-agent taxane therapy – Gemcitabine – Vinorelbine
  - Single-agent anthracycline therapy – Infusional 5FU – ***nab – paclitaxel (Abraxane)***
  - Capecitabine – liposomal doxorubicin
- Clinical trials- Refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov

Her-2/neu overexpression (3+ immunoperoxidase staining and/or 2+, 3+ by FISH) Patients

- Trastuzumab combinations are considered optimal first-line therapy (not for use with anthracyclines). Alternatively, trastuzumab alone can be given to patients who are unwilling or not suitable candidates for chemotherapy. Trastuzumab combinations include:
  - Trastuzumab – Paclitaxel – ***Trastuzumab – Vinorelbine***
  - Trastuzumab – Paliltaxel – Carboplatin – ***Trastuzumab – Capecitabine***
  - Trastuzumab – Docetaxel – ***Trastuzumab – Gemcitabine***
  - Trastuzumab – Docetaxel – Carboplatin
- Clinical trials –Refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov

General Considerations regarding therapy choices:

- Many chemotherapy combinations have been tested and have shown improved response rates ***compared to single agents***. However, these combinations are generally more toxic than single agent therapy and most have shown no improvement in survival. Combination therapy over single agents should be considered in patients with good PS and in those with aggressive disease ***and visceral threat.***
- If the patient has received prior anthracycline therapy, further anthracycline therapy may be considered if cardiac ***ejection fraction is normal***. Additional options to consider include the use of a less toxic anthracycline (eg. epirubicin), liposomal doxorubicin, or a cardioprotectant (dexrazoxane).
- Patients with bone disease (especially those with lytic changes on x-ray) should be considered for bisphosphonate therapy in addition to chemo- or hormonal therapy. EBRT should be reserved for painful metastases or for lesions in which pathologic fractures are imminent or have already occurred.In general, bisphosphonate therapy should continue regardless of changes in a patient's chemotherapy regimen.
- Special considerations - see last page of guideline for treatment of patients with solitary metastases, spinal cord compression and other specialty situations.

Treatment of Subsequent Recurrences (Stages I – IIIC)

Prior to initiating additional salvage therapy, assess PS and goal of therapy. Patients with good PS (ECOG 0-1) who demonstrated a response to the last regimen may be considered for additional salvage therapy. It is imperative to look for evidence of response prior to initiating each cycle (eg. subjective improvement in tumor related symptoms). After initiation of therapy, it is best to administer at least 2-3 cycles prior to evaluation for response. Scans may be indicated to follow objective response.

- For patients who progress on hormone therapy but showed an initial response, another endocrine treatment should be considered. Patients with extensive visceral or immediate life threatening disease might be optimally treated with initial chemotherapy and then considered for maintenance treatment with hormone therapy. Treatment choices include one of the following:
  - if premenopausal
    - Oophorectomy, (either surgical or medical with a GNRH analog) + tamoxifen, or megestrol acetate
  - if postmenopausal
    - Aromatase inhibitor (except aminoglutethimide)
    - Faslodex
    - Megestrol acetate

Note: The suggested order of sequence is based upon side effects and response rates. Patients with HER-2/neu positive disease are less likely to respond to hormone therapy and may have a shorter duration of response.

- For patients who recur following adjuvant chemotherapy, the treatment will depend on a number of factors, including time of recurrence, previous therapy, patient symptoms, PS, and other patient specific considerations. Treatment can include combination or single-agent chemotherapy:

  Combination Therapy
  - Anthracycline-based therapy
  - Doxorubicin – taxane
  - ***Capecitabine – taxane (docetaxel or paclitaxel)***
  - ***Gemcitabine – Paclitaxel***
  - ***Carboplatin – Paclitaxel (randomized trials have not been performed with this combination)***
  - CMF

  Single-Agent Therapy (***numerous combinations of the following agents have been studied in phase II trials. Many have shown efficacy but none have shown benefit over single agent therapy.***)
  - Single-agent taxane therapy
  - Single-agent anthracycline therapy
  - Capecitabine
  - liposomal doxorubicin
  - vinorelbine
  - gemcitabine
  - Infusional 5FU
- For patients with Her-2/neu protein overexpression (3+ immunoperoxidase staining and/or FISH+) who have progressed following first-line transuzumab –chemotherapy, it is controversial whether trastuzumab plus another chemotherapy agent should be used as opposed to using chemotherapy alone. Trastuzumab alone is FDA approved as second line after progression on chemotherapy (without trastuzumab). However, in today's clinical practice, most patients receive trastuzumab initially :
  - Trastuzumab – Paclitaxel
  - Trastuzumab – Paliclaxel – Carboplatin
  - Trastuzumab – Docetaxel
  - Trastuzumab – Docetaxel – Carboplatin
  - ***Trastuzumab – Vinorelbine***
  - ***Trastuzumab – Capecitabine***
  - ***Trastuzumab – Gemcitabine***

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BREAST CANCER, FEMALE Stage IV

Diagnostic Work-up

Stage IV

To make the diagnosis:
- bilateral mammography
- biopsy of *lesion* (core, incisional or excisional)

Initial Work-up Consists of the following:
- History and physical exam
- CBC, Plts & Diff., Chem panel
- Review pathology results
- Bone scan
- CXR
- CT scan of abdomen.
- *Baseline* MUGA scan or Echo if clinically indicated for patients receiving anthracycline or trastuzumab
- ***Check a baseline head MRI or CT scan for patients that may receive the bevacizumab – paclitaxel combination***
- Evaluate the following prognostic factors:
  - ***Disease burden***
  - ER/PR levels
  - menopausal status
  - HER-2/neu status (if not done at the time of the primary diagnosis). At this time, the optimal method of testing HER- 2/neu overexpression (immuno-histochemistry vs. FISH) remains undefined. Some experts agree that if HER-2/neu by immuno-histochemistry is 0, 1+ or 3+, the results are reliable. However, if 2+, ***FISH testing is recommended.*** Testing should be performed at experienced testing centers.

Staging

Stage IV :
5yr survival: 10%
Any T, any N, M1

Initial Treatment

Local Disease
- External beam radiotherapy or a hygienic mastectomy may be recommended to control local disease.
- ***Single isolated cranial or pulmonary metastases should be considered for surgical resection or radiosurgery [note: radiosurgery does not apply to pulmonary lesions]***
- ***Most patients with brain metastases should receive radiation therapy***
- ***Patients with spinal cord compression should receive palliative radiation. Surgical decompression may be considered for selected cases***
- ***Patients with an isolated bone metastasis may be considered for palliative radiation therapy only.***
- ***May consider intrathecal liposomal Ara-C (DepoCyt), intrathecal MTX, appropriate***
- ***Systemic chemotherapy or palliative radiation for patients with meningeal disease.***

Hormone Receptor Positive with bone/soft tissue disease only:
- Hormone therapy can be considered (except in the event of life threatening visceral disease).
  - Tamoxifen
  - Toremifene
  - aromatase inhibitors (eg, anastrozole, letrozole)
  - Faslodex

  Note: (Als, faslodex & letrozole are for postmenopausal women only)
- oophorectomy is an option for premenopausal women
- GNRH analogs (premenopausal women only)
- Megace.

Hormone Receptor positive with symptomatic visceral disease:
Patients with extensive visceral or immediate life-threatening disease might be optimally treated with initial chemotherapy and then considered for maintenance treatment with hormone therapy.

Combination Therapy
- Anthracycline-based therapy (AC, FAC, CAF, FEC, CEF, EC)
- Doxorubicin – Taxane (doxorubicin – paclitaxel or doxorubicin – docetaxel)
- ***Capecitabine – Taxane (docetaxel or paclitaxel)***
- ***Gemcitabine – Paclitaxel***
- ***Bevacizumab – Paclitaxel***
- CMF
- ***Carboplatin – Paclitaxel (randomized trials have not been performed with this combination)***

Single Agent Therapy (***numerous combinations of the following agents have been studied in phase II trials. Many have shown efficacy but none have shown benefit over single-agent therapy.***)
- Single-agent taxane therapy (paclitaxel or docetaxel)
- Single-agent anthracycline therapy (doxorubicin or epirubicin)
- Capecitabine
- Vinorelbine
- Gemcitabine
- Infusional 5FU
- Liposomal doxorubicin
- ***nab – paclitaxel (Abraxane)***

Note: Treatment choice will depend on a number of factors, including previous therapy, patient symptoms, performance status, and other patient specific considerations.

Hormone receptor negative OR visceral disease should receive chemotherapy as listed above.

High-Risk, Node Negative or microscopically involved nodes:
- For patients with high-risk, node-negative disease or microscopically involved nodes [pN1mi or pN0 (i+)] consideration can be given to the use of regimens for node-positive disease. In general, the benefit is proportional to the risk so one must factor in the associated toxicities and durations of therapy.

Her-2/neu overexpression (3+ immunoperoxidase staining and/or 2+,3+ by FISH) Patients
- For patients with Her-2/neu protein overexpression (3+ immunoperoxidase staining and/ or FISH+) trastuzumab combinations are considered optimal first-line therapy (not for use with anthracyclines). Alternatively, trastuzumab alone can be given to patients who are unwilling or not suitable candidates for chemotherapy. :
  - Trastuzumab – Paclitaxel
  - Trastuzumab – Paliclitaxel – Carboplatin
  - Trastuzumab – Docetaxel
  - Trastuzumab – Docetaxel – Carboplatin
  - ***Trastuzumab – Vinorelbine***
  - ***Trastuzumab – Capecitabine***

  Note: Patients with metastatic breast cancer should have their HER-2/neu status assessed if it was not done at the time of the primary diagnosis. The current FDA recommendation is to treat patients with a 2+ or 3+. See "Emerging Issues" regarding 2+ HER-2 overexpression.
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/
- Best supportive care only and referral to hospice if patient has poor performance status.

General Considerations regarding therapy choices:
- Many chemotherapy combinations have been tested and have shown improved response rates ***compared with single agents.*** However, these combinations are generally more toxic than single agent therapy and most have shown no improvement in survival. Combination therapy over single agents should be considered in patients with good PS and in those with aggressive disease ***and visceral threat.***
- If the patient has received prior anthracycline therapy, further anthracycline therapy may be considered if cardiac ***ejection fraction is normal.*** Additional options to consider include the use of a less toxic anthracycline (eg, epirubicin), liposomal oxorubicin, or a cardioprotectant (dexrazoxane).
- Patients with bone disease (especially those with lytic changes on x-ray) should be considered for bisphosphonate therapy in addition to chemo- or hormonal therapy. EBRT should be reserved for painful metastases or for lesions in which pathologic fractures are imminent or have already occurred. In general, bisphosphonate therapy should continue regardless of changes in a patient's chemotherapy regimen.
- Special considerations - see last page of guideline for treatment of patients with solitary metastases, spinal cord compression and other specialty situations.

Adjuvant Treatment

Stage IV
Clinical trials - Please refer to the following website for available clinical trials:
http://cancertrials.nci.nih.gov/

Subsequent Recurrent/Refractory Treatment

Stage IV
Metastatic recurrence:
Note: Patients with metastatic breast cancer should have their HER-2/neu status assessed if it was not done at the time of primary diagnosis. The current FDA recommendation is to treat patients who are 2+ or 3+ with trastuzumab. See "Emerging Issues" regarding 2+ HER-2/neu overexpression.

Hormone receptor positive, and bone/soft tissue disease only:
- For patients who have had prior anti-estrogen within the past year, strong consideration should be given to additional 2nd line hormonal therapy.
- For patients who have had no prior anti-estrogen or who are more than 1 year off of an anti-estrogen:
  - If pre-menopausal: Tamoxifen, an LHRH Agonist, an oophorectomy or combination of some of these
  - If post-menopausal: tamoxifen, toremifene, or an AI (depending on previous treatment)
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Hormone receptor positive with symptomatic visceral disease:
- Patients with extensive visceral or immediate life threatening disease might be optimally treated with initial chemotherapy and then considered for maintenance treatment with hormone therapy. Treatment choices include one of the following:

  Combination Therapy
  - Anthracycline-based therapy (AC, FAC, CAF, FEC, CEF, EC)
  - Doxorubicin – taxane (doxorubicin – paclitaxel or doxorubicin – docetaxel)
  - ***Capecitabine – taxane (docetaxel or paclitaxel)***
  - CMF

  Single Agent Therapy
  - Single-agent taxane therapy
  - Single-agent anthracycline therapy
  - Capecitabine
  - Gemcitabine
  - Infusional 5FU
  - liposomal doxorubicin
  - Vinorelbine
  - ***nab – paclitaxel (Abraxane)***
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Hormone receptor negative, pre- and postmenopausal patients:
- For patients who progress on chemotherapy, the treatment will depend on a number of factors, including previous therapy, patient symptoms, PS, and other patient specific considerations. Treatment can include combination or single-agent chemotherapy.

  Combination Therapy
  - Anthracycline-based therapy (AC, FAC, CAF, FEC, CEF, EC)
  - Doxorubicin – taxane (doxorubicin – paclitaxel or doxorubicin – docetaxel)
  - ***Capecitabine – taxane (docetaxel or paclitaxel)***
  - CMF

  Single Agent Therapy
  - Single-agent taxane therapy
  - Single-agent anthracycline therapy
  - Capecitabine
  - Gemcitabine
  - Infusional 5FU
  - liposomal doxorubicin
  - Vinorelbine
  - ***nab – paclitaxel (Abraxane)***
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

Her-2/neu overexpression (3+ immunoperoxidase staining and/or 2+,3+ by FISH) Patients
- For patients with Her-2/neu protein overexpression (3+ immunoperoxidase staining and/or FISH+) who have progressed following first-line transuzumab – chemotherapy, it is controversial whether trastuzumab plus another chemotherapy agent should be used as opposed to using chemotherapy alone. Trastuzumab alone is FDA approved as second line after progression on chemotherapy (without trastuzumab). However, in today's clinical practice, most patients receive trastuzumab initially :
  - Trastuzumab alone
  - Trastuzumab – Paclitaxel
  - Trastuzumab – Paliclitaxel – Carboplatin
  - Trastuzumab – Docetaxel
  - Trastuzumab – Docetaxel – Carboplatin
  - ***Trastuzumab – Vinorelbine***
  - ***Trastuzumab – Capecitabine***
- Clinical trials - Please refer to the following website for available clinical trials: http://cancertrials.nci.nih.gov/

General Considerations regarding therapy choices:
- Many chemotherapy combinations have been tested and have shown improved response rates. However, these combinations are generally more toxic than single agent therapy and most have shown no improvement in survival. Combination therapy over single agents should be considered in patients with good PS and in those with aggressive disease.
- If the patient has received prior anthracycline therapy, further anthracycline therapy may be considered if cardiac status is stable. Additional options to consider include the use of a less toxic anthracycline (eg, epirubicin), liposomal doxorubicin, or a cardio-protectant (dexrazoxane).
- Patients with bone disease (especially those with lytic changes on x-ray) should be considered for bisphosphonate therapy in addition to chemo- or hormonal therapy. EBRT should be reserved for painful metastases not controlled by bisphosphonates or for lesions in which pathologic fractures are imminent or have already occurred. In general, bisphosphonate therapy should continue regardless of changes in a patient's chemotherapy regimen.
- Special considerations - see last page of guideline for treatment of patients with solitary metastases, spinal cord compression and other specialty situations.

Monitoring/Follow-Up

Stage IV
- History and physical exam tailored to disease progression and therapy chosen. Routine use of X-rays, scans and serum markers in patients without symptoms is not recommended.
- Patients receiving tamoxifen should have a yearly gynecologic exam (if no prior hysterectomy) and should be carefully questioned regarding vaginal discharge or bleeding
- Patients receiving an aromatase inhibitor should have periodic monitoring of bone mineral density. Anti-resorptive therapy (preferable a non-SERM) should be considered if bone mineral density is depressed ***and all patients should take calcium and vitamin D***
- The use of serum markers for following response in patients with recurrent disease should be restricted to patients in whom other objective measures are equivocal.
- ***Patients receiving bevacizumab – paclitaxel should be routinely monitored for hypertension, proteinuria, and bleeding. Cardiovascular events should be carefully monitored for but the benefits of the regimen clearly outweigh the risks.***
- ***Patients receiving trastuzumab should have cardiac monitoring at 3, 6, and 12 months after beginning trastuzumab therapy. Trastuzumab therapy should be withheld for the following:***
  - ***If ejection fraction drops more than 10% below the institutional normal***
  - ***If the EF drops more than 15% overall***
  - ***Clinical CHF with a documented drop in EF***
  - ***If EF normalizes within 4 weeks may consider resuming trastuzumab therapy***

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Endocrine Regimens

AROMATASE INHIBITORS

Anastrozole
Anastrozole 1 mg PO QD
For adjuvant therapy, continue for 5 years.
For Stage IV disease, continue until disease progression
Lancet 2002; 359:2131-2139.
Cancer 2003; 98:1802-1810.

Letrozole
Letrozole 2.5 mg PO daily until disease progression
JCO 2003; 21:2101-2109.
The Oncologist 2004; 9:497-506.

Exemestane (Aromasin)
Exemestane 25 mg PO daily
N Engl J Med, 2004; 350:1081-1092. (adjuvant)
J Clin Oncol, 2000; 18:1399-1411. (metastatic)

LHRH AGAONISTS

Goserelin
Goserelin acetate 3.6 mg SQ day 1
Repeat every 28 days x 2 years
Euro J Cancer, 2003; 39: 1711-1717 (adjuvant therapy)
or
Goserelin acetate 10.8 mg SQ day 1
Repeat every 3 months
JCO 1993;11:1529. (metastatic)

Goserelin + Tamoxifen
Goserelin 3.6 mg subcutaneously every 28 days for 3 years
Tamoxifen 20 mg PO daily for 5 years
JCO 2002; 20:4621-4627.

Leuprolide (monthly)
Leuprolide 7.5 mg IM day 1
Repeat every 28 days

Leuprolide (Q3 mo)
Leuprolide 22.5 mg IM day 1
Repeat every 3 months
* Leuprolide not FDA approved for breast cancer

OTHER

Faslodex
Faslodex 250mg IM Q28 days
J Clin Oncol, 2004; 22:1605-1613.

Megestrol acetate
Megestrol acetate 40 mg PO QID
Semin Oncol 1986; 13: 9 – 14

Tamoxifen
Tamoxifen 20 mg PO QD
Begin 2 – 5 weeks post-operatively
For adjuvant therapy, continue for 5 years. For Stage IV disease, continue until disease progression
J Clin Oncol, 2003; 21:2276–2281.

Toremifene
Toremifene 60 mg PO daily
JCO 1995;13:2556-2566.

Chemotherapy Regimens

Note: Mitoxantrone may be substituted for doxorubicin in patients who are elderly, or have cardiovascular disease, or have received prior anthracycline therapy. A = Adjuvant M = Metastatic Neo = neoadjuvant

Neoadjuvant Regimens

Docetaxel – Capecitabine
Docetaxel 75 mg/m² IV over 1 hour day 1
Capecitabine 1,000 mg/m² PO BID days 1 – 14
Repeat every 21 days x 4 cycles
ESMO 2004; abstract 215

Doxorubicin – Paclitaxel
Doxorubicin 60 mg/m² IV bolus over 5 – 15 minutes day 1
Paclitaxel 200 mg/m² IV over 3 hours day 1
Repeat every 21 days x 4 cycles
JCO 2004; 22:4958-4965.

Adjuvant Regimens

AC (A, M, Neo)
Doxorubicin 60mg/m² IVB day 1
Cyclophosphamide 600mg/m² IVB day 1
Repeat every 21 days x 4 cycles
JCO 1990; 8:1483 – 1496.

CAF (A, M, Neo)
Cyclophosphamide 500mg/ m² IV day 1
Doxorubicin 50mg/ m² IV day 1
5FU 500 mg/ m² IV day 1
Repeat every 21 days x 6 cycles
Breast Can Res & Treat. 1983;3:209 – 220. ***(metastatic)***
Proc Am Soc Clin Oncol. 1998;17:1a. Abstract 2

FAC (A, M, Neo)
5FU 500mg/m² IVB days 1 & 8
Doxorubicin 50mg/m² IVB day 1
Cyclophosphamide: 500mg/m² IVB day 1
Repeat every 21 -28 days x 6 cycles
Ann Int Med 1979; 91:847

CEF (A, M Neo)
Cyclophosphamide 75 mg/m² PO days 1 – 14
Epirubicin 60 mg/m² IV days 1 and 8
5FU 500 mg/m² IV days 1 and 8
Repeat cycle every 28 days x 6 cycles
JCO 1998; 16: 2651-2658

FEC-100 (A, M Neo)
5FU 500 mg/m² IV day 1
Epirubicin 100 mg/m² IV day 1
Cyclophosphamide 500 mg/m² IV day 1
Repeat cycle every 21 days x 6 cycles
JCO 2001; 19: 602-611. (adjuvant)
JCO 2004; 22:3070-3079

FEC-100 — Docetaxel (A)
FEC-100 doses as above
Repeat FEC-100 every 21 days x 3 cycles followed by
Docetaxel 100 mg/m² IV day 1
Repeat every 21 days x 3 cycles
SABC Symposium 2004. Abstract 27.

EC (A, M)
Epirubicin 100mg/m² IV day 1
Cyclophosphamide 830mg/m² IV day 1
Repeat cycle every 21 days
JCO 2001; 19: 3103 – 3110 (adjuvant)

CMF (IV CTX) (A, M, Neo)
Cyclophosphomide 600 mg/m² IV day 1
Methotrexate 40 mg/m² IV day 1
5FU 600 mg/m² IV day 1
Repeat cycle Q21 days
Am J Med. 1987; 83:455

CMF (IV-CTX: D1,8) (A, M, Neo)
Cyclophosphamide 600mg/m² IV days 1 & 8
Methotrexate 40mg/m² IVB on days 1 & 8
5FU 600mg/m² IVB days 1 and 8
Repeat cycle Q 28 days x 6 cycles
Br J Cancer, 1999: 81 (2): 316-322 (metastatic ref)

CMF (Oral - CTX) (A, M, Neo)
Cyclophosphamide 100 mg/m² PO days 1 – 14
Methotrexate 40 mg/m² IV days 1, 8
5FU 600 mg/m² IV days 1, 8
Repeat cycle Q28 days x 6 cycles
JCO 1990; 8(9):1483

Adjuvant Regimens (con't)

AC → Paclitaxel (A, Neo)
Doxorubicin 60mg/m² IVB day 1
Cyclophosphamide 600mg/m² IVB day 1
Repeat every 21 days x 4 cycles followed by
Paclitaxel 175 mg/m² IV day 1
Repeat every 21 days x 4 cycles
JCO 2003; 21:976-983.

AC → Docetaxel (A, Neo)
Doxorubicin 60mg/m² IV day 1
Cyclophosphamide 600mg/m² IV day 1
Repeat every 21 days x 4 cycles
then
Docetaxel 100mg/m² IV day 1
Repeat every 21 days x 4 cycles
JCO 2003;21:4165

TAC
Taxotere 75 mg/m² IV day 1
Doxorubicin 50 mg/m² IV day 1
Cyclophosphamide 500 mg/m² IV day 1
Repeat every 21 days x 6 cycles
Proc Am Soc Clin Oncol. 2002; 36a. Abstract 141.
SABCS 2003; abstract 43

Dose-Dense AC — Paclitaxel
Doxorubicin 60mg/m² IV day 1
Cyclophosphamide 600mg/m² IV day 1
Repeat every 14 days x 4 cycles followed by
Paclitaxel 175 mg/m² IV day 1 administered every 14 days x 4 cycles
G-CSF 300 or 480 mcg days 3 – 10 of each cycle
JCO 2003; 21:1431 – 1439.

Epirubicin – Tamoxifen (adjuvant for elderly)
Epirubicin 30 mg IV days 1, 8, 15
Tamoxifen 30 mg PO daily for 3 years
Repeat epirubicin every 28 days for 6 cycles
JCO 2004; 22:4674-4682.

AC — Paclitaxel + Trastuzumab
Doxorubicin 60mg/m² IV day 1
Cyclophosphamide 600mg/m² IV day 1
Repeat every 21 days x 4 cycles followed by
Paclitaxel 80 mg/m² IV weekly x 12 weeks is preferred (or 175 mg/m² IV day 1 every 21 days x 4 cycles)
Trastuzumab 4mg/kg loading dose for the 1st week followed by 2 mg/kg weekly for 51 weeks (total trastuzumab = 1 year). Trastuzumab should be given concurrently with Paclitaxel
Late-breaking session ASCO 2005 presented on May 16th, 2005 (results of NSABP-31/NCCTG N-9831)

Capecitabine Dose Calculation According to Body Surface Area

Dose level 2500 mg/m2/day		Number of tablets to be taken at each dose (morning and evening)	
Surface Area (m2)	Total Daily* Dose (mg)	150 mg	500 mg
≤ 1.24	3000	0	3
1.25 - 1.36	3300	1	3
1.37 - 1.51	3600	2	3
1.52 - 1.64	4000	0	4
1.65 - 1.76	4300	1	4
1.77 - 1.91	4600	2	4
1.92 - 2.04	5000	0	5
2.05 - 2.17	5300	1	5
≥ 2.18	5600	2	5

* Total Daily Dose divided by 2 to allow equal morning and evening dose

Metastatic Combination Regimens

Doxorubicin – Docetaxel
Doxorubicin 50 mg/m² IV over 15 minutes on day 1 followed by
Docetaxel 75 mg/m² IV over 1 hour on day 1
Repeat every 21 days
JCO 2003; 21:968-975.

Doxorubicin – Paclitaxel
Doxorubicin 50 mg/m² IV day 1
Paclitaxel 150 mg/m² IV day 1
Repeat cycle every 21 days
Note: CSF support administered
JCO 2003; 21:588-592.

Docetaxel – Capecitabine
Docetaxel 75 mg/m² IV over 1 hour day 1
Capecitabine 1,250 mg/m² PO BID days 1 – 14
Repeat every 21 days
J Clin Oncol, 2002; 20:2812-2823. (1st and 2nd line metastatic)

Paclitaxel – Capecitabine
Paclitaxel 175 mg/m² IV over 3 hours day 1
Capecitabine 825 mg/m² PO BID days 1 – 14
Repeat every 21 days
JCO 2004; 22:2321 – 2327.

Trastuzumab – Paclitaxel
Trastuzumab Loading dose: 4 mg/kg IV over 90 minutes x 1
Maintenance dose: 2 mg/kg IV weekly over 30 minutes (if initial loading dose well tolerated)
Paclitaxel 175 mg/m² IV over 3 hours
Repeat Q21 days x 6 cycles
ASCO Proceedings 1998; 17: abstract 377

Trastuzumab – Paclitaxel – Carboplatin
Carboplatin AUC 6 IV on day 1
Paclitaxel 175 mg/m² IV over 3 hours
Trastuzumab 4mg/kg loading dose followed by a weekly dose of 2 mg/kg
Repeat every 21 days x 6 cycles
SABCS 2002; abstract 35.

Trastuzumab – Docetaxel
Docetaxel 100 mg/m² IV day 1
Trastuzumab 4mg/kg loading dose followed by a weekly dose of 2 mg/kg
Repeat every 21 days x 6 cycles (Herceptin continued until disease progression)
SABCS 2003; abstract 217.
JCO 2004; 22:1071 – 1077 (docetaxel may also be administered as 35 mg/m² weekly x 6 weeks; cycles repeated every 8 weeks)

Trastuzumab – Docetaxel – Carboplatin
Carboplatin AUC 6 IV day 1
Docetaxel 75 mg/m² IV day 1
Trastuzumab 4mg/kg loading dose followed by weekly 2 mg/kg
Repeat every 21 days x 6 cycles (continue trastuzumab for 1 year or until disease progression
JNCI 2004;96:759-769.

Trastuzumab – Vinorelbine
Trastuzumab 4mg/kg loading dose followed by weekly 2 mg/kg
Vinorelbine 25 mg/m² IV weekly over 10 min following trastuzumab
Repeat weekly until progression
JCO 2003; 21:2889-2895.

Trastuzumab – Capecitabine
Trastuzumab 4mg/kg loading dose followed by weekly 2 mg/kg
Capecitabine 1250 mg/m² PO BID days 1 – 14 (max of 6 cycles)
Repeat every 21 days (trastuzumab may be con't until disease prog.)
SABCS 2004; abstract 3049.

Trastuzumab – Gemcitabine
Trastuzumab 4mg/kg loading dose followed by weekly 2 mg/kg
Gemcitabine 1,200 mg/m² IV days 1 and 8
Repeat gemcitabine every 21 days
Clin Breast Cancer. 2004; 5:142-147.

Gemcitabine – Paclitaxel
Gemcitabine 1,200 – 1,250 mg/m² IV on days 1 and 8
Paclitaxel 175 mg/m² IV on day 1
Repeat every 21 days for 8 cycles
Oncology 2004; 66:18 – 23. (G = 1,200 mg/m²)
Proc Am Soc Clin Oncol. 2004; 22: Abstract 510 (G = 1,250 mg/m²)

Bevacizumab – Paclitaxel
Bevacizumab 10 mg/m² on days 1 and 15
Paclitaxel 90 mg/m² on days 1, 8, 15
Repeat every 28 days
Late-breaking ASCO 2005 abstract presented on May 16th, 2005

Carboplatin – Paclitaxel (weekly)
Carboplatin AUC 2 IV day 1
Paclitaxel 100 mg/m² IV day 1
Repeat cycles weekly
JCO 2002; 20:3857-3864.

Single-Agent Metastatic Regimens

Docetaxel
Docetaxel 60 – 100 mg/m² IV day 1
Repeat every 21 days
J Clin Oncol, 1998; 16:3362-3368.

Docetaxel (Weekly)
Docetaxel 35 – 40 mg/m² IV day 1 weekly x 6 weeks
Repeat every 8 weeks
JCO 2000;18:1212-19 (40 mg/m²)
JCO 2001;19:3500-3505 (36 mg/m²)

Doxorubicin
Doxorubicin 60 mg/m² IV day 1
Repeat cycle Q21 – 28 days
Drugs. 1992;44(Suppl 4):17.
Am JCO. 1989;12:57 – 62.
JCO 2003; 21:588-592

Doxorubicin (weekly)
Doxorubicin 20 mg/m² IV weekly
Eur J Cancer. 1994;30A:1775.

5FU
5FU 300 mg/m²/day CIV
Continue until progression or unacceptable toxicity.
JCO. 1995;13: ***419 – 423.***

Epirubicin
Epirubicin 70 mg/m² IV days 1 and 8
Repeat every 28 days
Cancer Chemother Pharmacol 2000;46:459-466
OR
Epirubicin 90 mg/m² IV day 1
Repeat every 21 days
Br J Cancer 1998;77:2257-2263.

Trastuzumab
Trastuzumab Loading dose 4 mg/kg IV over 90 minutes x 1;
Maintenance dose 2 mg/kg IV weekly over 30 minutes
(if initial loading dose well tolerated)
ASCO Proceedings 1998;17:abstract 376.

Capecitabine
Capecitabine 2510 mg/m² PO QD (divided dose given twice daily) days 1 – 14
Repeat Q21 days
JCO 1999; 17: 485-493.

Capecitabine (elderly)
Capecitabine 1,000 mg/m² PO daily (divided dose given BID) days 1 – 14
Repeat cycle every 21 days
JCO 2005 (early release)

Paclitaxel
Paclitaxel 175 mg/m² IV day 1 over 3 hours or over 24 hours
Repeat every 21 days
JCO 1995; 13:2575
JCO 2003; 21:588-592

Paclitaxel (Weekly)
Paclitaxel 60 – 90 mg/m² IV day 1
Repeat weekly
JCO 1998;16:3353-3361 ***(reference uses 100 mg/m² weekly)***

Vinorelbine
Vinorelbine 30 mg/ m² IV day 1
Repeat every 7 days
JCO 1995;13:2567.

Gemcitabine
Gemcitabine 1200 mg/m² days 1,8,15
Repeat Q28 days
Breast Cancer Res Treat 2001;66: 83 – 87
Oncology 2002;62:2-8

Liposomal doxorubicin
Liposomal doxorubicin 50 mg/m² IV day 1
Repeat every 21 – 28 days
J Clin Oncol 2004; 22:3893 – 3901.

Liposomal Ara-C (intrathecal)
50 mg IT Q2 weeks x 1 month.

Intrathecal Methotrexate
12mg IT 1-2 times per week initially followed by
therapy every 1-2 weeks after symptom improvement

nab – paclitaxel (Abraxane)
nab – paclitaxel 260 mg/m² IV over 30 minutes day 1
Repeat every 3 weeks
SABCS 2003; abstract 44

nab – paclitaxel (Abraxane – weekly)
nab – paclitaxel 125 mg/m² IV over 30 minutes day 1 weekly x 3
Repeat every 4 weeks
ASCO 2004 (O'Shaughnessy J et al)

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Radiation

Stage 0 - DCIS
- 4500-5040 cGy is delivered to the entire breast in daily fractions of 180-200 cGy. Radiation is delivered through tangential opposed fields.

A boost of 1000-1500 to the primary site may be considered

Stage I
A dose of 4500-5040 cGy to the entire breast delivered at 180-200 cGy/day 5 days/week. A boost of 1000-2000 cGy is usually delivered to the tumor bed.

Palliative Regimens - Examples of possible radiation regimens follow - there are other acceptable regimens

Spinal Cord Compression
Acceptable regimens include the following:
- 400 cGy x 3, then 200 cGy x 12
- 300 cGy x 10 to total 3000 cGy
- 250 cGy x 15 to total 3750 cGy
- 200 cGy x 20 to total 4000 cGy

Bone Metastases
Acceptable regimens include the following:
- 800-1000 cGy in 1 fraction
- 400 cGy x 5
- 300 cGy x 10
- 250 cGy x 15-16

Stage II
A dose of 4500-5040 cGy to the entire breast ± nodes delivered at 180-200 cGy/day 5 days/week. A boost of 1000-2000 cGy is usually delivered to the tumor bed.

Palliative Regimens - Examples of possible radiation regimens follow - there are other acceptable regimens

Spinal Cord Compression
Acceptable regimens include the following:
- 400 cGy x 3, then 200 cGy x 12
- 300 cGy x 10 to total 3000 cGy
- 250 cGy x 15 to total 3750 cGy
- 200 cGy x 20 to total 4000 cGy

Bone Metastases
Acceptable regimens include the following:
- 800-1000 cGy in 1 fraction
- 400 cGy x 5
- 300 cGy x 10
- 250 cGy x 15-16

Stage IIIA
A dose of 4500-5040 cGy to the entire breast and nodal regions delivered at 180-200 cGy/day 5 days/week. A boost of 1000-2000 cGy is usually delivered to the tumor bed.

Palliative Regimens - Examples of possible radiation regimens follow - there are other acceptable regimens

Spinal Cord Compression
Acceptable regimens include the following:
- 400 cGy x 3, then 200 cGy x 12
- 300 cGy x 10 to total 3000 cGy
- 250 cGy x 15 to total 3750 cGy
- 200 cGy x 20 to total 4000 cGy

Bone Metastases
Acceptable regimens include the following:
- 800-1000 cGy in 1 fraction
- 400 cGy x 5
- 300 cGy x 10
- 250 cGy x 15-16

Stage IIIB
A dose of 4500-5040 cGy to the entire breast and nodal regions delivered at 180-200 cGy/day 5 days/week. A boost of 1000-2000 cGy is usually delivered to the tumor bed.

Palliative Regimens - Examples of possible radiation regimens follow - there are other acceptable regimens

Spinal Cord Compression
Acceptable regimens include the following:
- 400 cGy x 3, then 200 cGy x 12
- 300 cGy x 10 to total 3000 cGy
- 250 cGy x 15 to total 3750 cGy
- 200 cGy x 20 to total 4000 cGy

Bone Metastases
Acceptable regimens include the following:
- 800-1000 cGy in 1 fraction
- 400 cGy x 5
- 300 cGy x 10
- 250 cGy x 15-16

Stage IV
A dose of 4500-5040 cGy to the entire breast and nodal regions delivered at 180-200 cGy/day 5 days/week. A boost of 1000-2000 cGy is usually delivered to the tumor bed.

Palliative Regimens - Examples of possible radiation regimens follow - there are other acceptable regimens

Spinal Cord Compression
Acceptable regimens include the following:
- 400 cGy x 3, then 200 cGy x 12
- 300 cGy x 10 to total 3000 cGy
- 250 cGy x 15 to total 3750 cGy
- 200 cGy x 20 to total 4000 cGy

Bone Metastases
Acceptable regimens include the following:
- 800-1000 cGy in 1 fraction
- 400 cGy x 5
- 300 cGy x 10
- 250 cGy x 15-16

Breast Cancer - AJCC Staging Handbook - 6th Edition

Primary Tumor (T):

T1: Tumor 2.0 cm or less in greatest dimension
- T1mic: Microinvasion 0.1 cm or less in greatest dimension
- T1a: 0.5 cm or less
- T1b: More than 0.5 cm but not more than 1 cm in greatest dimension
- T1c: More than 1 cm but not more than 2 cm in greatest dimension

T2: Tumor more than 2 cm but not more than 5 cm in greatest dimension

T3: Tumor more than 5 cm in greatest dimension

T4: Tumor of any size with direct extension to chest wall or skin
- T4a: Extension to chest wall, not including pectoralis muscle
- T4b: Edema, ulceration of the skin of the breast, or satellite skin nodules confined to the same breast
- T4c: Both T4a and T4b
- T4d: Inflammatory carcinoma

Regional lymph nodes (N)

N0: No regional lymph node metastasis or only clumps of cells by immuno-histochemistry but not by H&E staining (N0(i+))
- pN0 (i-): No regional lymph node mets histologically, negative IHC
- pN0 (i+): No regional lymph node mets histologically, positive IHC, no IHC cluster > 0.2 mm
- pN0 (mol -): negative molecular findings
- pN0 (mol +): positive molecular findings

N1: Metastasis to movable ipsilateral axillary lymph node(s)
- pN1: metastases in 1 – 3 axillary lymph nodes and/or in internal mammary nodes with microscopic disease detected by SLND but not clinically
- pN1a: 1 – 3 axillary nodes
- pN1b: Mets in internal mammary nodes with microscopic disease detected by SLND but not clinically apparent
- pN1c: metastases in 1 – 3 axillary lymph nodes and in internal mammary nodes with microscopic disease detected by SLND but not clinically

N2: Metastasis to ipsilateral lymph node(s) fixed or matted or in clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastases
- pN2: Metastases in 4 – 9 axillary lymph nodes or in clinically apparent ipsilateral internal mammary nodes in the absence of clinically evident axillary lymph node metastases
- pN2a: metastases in 4 – 9 nodes with at least one tumor deposit > 2.0 mm
- pN2b: Mets in clinically apparent internal mammary nodes in the absence of axillary lymph node metastases
- N2a: Metastasis in ipsilateral axillary lymph node(s) fixed or matted to one another or to other structures
- N2b: Metastases only in clinically apparent ipsilateral internal mammary nodes and in the absence of clinically evident axillary lymph node metastases

N3: Metastases in ipsilateral infraclavicular lymph nodes with or without axillary lymph node involvement or in clinically apparent ipsilateral nodes and in the presence of clinically evident axillary lymph node metastases; or metastases in ipsilateral supra-clavicular lymph nodes with or without axillary or internal mammary lymph node involvement
- pN3: metastases in 10 or more axillary lymph nodes, infraclavicular lymph nodes or in clinically apparent ipsilateral internal mammary lymph nodes in the presence of 1 or more positive nodes or in > 3 nodes with clinically negative micro-scopic metastasis in internal mammary nodes; or in ipsilateral supraclavicular nodes.
- N3a/pN3a: Metastases in 10 or more axillary nodes or metastases to the ipsilateral infraclavicular lymph nodes
- N3b/pN3b: Metastases in ipsilateral internal mammary lymph nodes and axillary lymph nodes
- N3c/pN3c: Metastases in ipsilateral supra-clavicular lymph nodes

Distant Metastases (M)

M0: No distant metastasis

M1: Distant metastasis present

Patient Education

LCIS
- Perform monthly breast exam
- Recommend screening and counseling of relatives if a positive family history is identified (males, if carriers also need counseling)
- Tamoxifen information
- Lifestyle modifications
  - weight loss
  - decrease alcohol consumption
  - low fat diet
  - increase exercise
- Educate women about symptoms of recurrence

DCIS
- Perform monthly breast exam
- Recommend screening and counseling of female relatives if a positive family history is identified
- Tamoxifen information
- Lifestyle modifications
  - weight loss
  - decrease alcohol consumption
  - low fat diet
  - increase exercise
- Educate women about symptoms of recurrence

Stages I - IV
- Recommend joining a self help or support group (for Stage I - IV patients)
- Perform monthly breast exam
- Recommend screening and counseling of female relatives if a positive family history is identified
- Educate women about symptoms of recurrence
- Inform care provider about use of alternative medicines such as herbs (some can lead to interactions with other drugs)
- Lifestyle modifications
  - weight loss
  - decrease alcohol consumption
  - low fat diet
  - increase exercise
- ***Patients on statin therapy for lipid management should also be made aware that it may also be associated with a decrease in the risks of breast and colon cancers.***

Drug Complications

5FU:
Most Common: Myelosuppression: granulocytopenia nadir : 7-14 days; thrombocytopenia nadir : 7-14 days
Gastrointestinal: nausea and vomiting, stomatitis, diarrhea, proctitis, esophagitis
Less Common: Alopecia; hyperpigmentation of nail bed, face and hands; partial loss of nails; maculopapular rash
Rarely: Acute cerebellar syndrome

Cyclophosphamide:
Most Common: Leukopenia, nadir occurs @ 7-14 days, recovery after 10 days, mild anemia, thrombocytopenia, hemorrhagic cystitis: 5-10% of patients, alopecia, anorexia, nausea, vomiting
Less Common: Amenorrhea, urticaria, transverse ridging of nails, skin hyperpigmentation, SIADH, hepatotoxicity
Rarely: Anaphylaxis, cardiotoxicity, pulmonary toxicity, increased incidence of transitional cell CA of the bladder.

Methotrexate:
Most Common: Nausea, vomiting, anorexia, stomatitis, diarrhea, myelosuppression with pancytopenia : RBC nadir 6-13 days; reticulocytes, 2-7 days; WBC's nadir: 4-7 days (rarely again at 12-21 days); platelet nadir: 5-12 days
Less Common: Hepatic fibrosis, cirrhosis (usually high dose MTX); renal tubular necrosis (high dose regimens); alopecia, dermatitis, pigment changes, dizziness, malaise, blurred vision
Rarely: Chills, fever, osteoporosis, conjunctivitis, anaphylaxis.

Tamoxifen:
Most Common: Mild and transient leukopenia and thrombocytopenia can occur in 5-10% of patients. Menopause-like symptoms; hot flashes, nausea, vomiting occur in < 25% of patients.
Less Common: vaginal bleeding, vaginal discharge, menstrual irregularities, pruritis vulvae, skin rashes, dizziness, headache, depression, lassitude, leg cramps, slight peripheral edema
Rare: Retinitis, pseudotumor cerebrae, deep-vein thrombosis

Doxorubicin:
Most Common: Myelosupression: mild to moderate, nausea, vomiting, diarrhea, alopecia
Less Common: Radiation cell recall reaction, radiosensitization, skin hyperpigmentation, dermal creases, fever, chills, allergic reaction, conjunctivitis.
Cumulative Dose Toxicity: Cardiac - CHF cardiomyopathy

Letrozole
Musculoskeletal pain, nausea, vomiting, headache, fatigue, diarrhea, constipation, hot flashes, peripheral edema.

Docetaxel
Leukopenia, nadir occurs @ 7-8 days, anemia, thrombocytopenia, fluid retention (peripheral edema), hypersensitivity reactions (including flushing rash, dyspnea, hypertension), , asthenia, nausea, vomiting, stomatitis, alopecia, transient skin changes, arthralgia and/or myalgia

Goserelin
Hot Flashes, Nausea/Vomiting, Impotence, Loss of libido

Prednisone
GI upset, peptic ulceration, higher susceptibility to infection, decreased glucose intolerance, electrolyte disturbance, paper- thin skin with striae, behavioral abnormalities, acne.

Dosing for Bisphosphonates
Pamidronate 90mg IV every 21 – 28 days
Zoledronic acid 4mg IV every 21 – 28 days

Toremifene
Hot flashes, sweating, nausea, vaginal discharge, dizzines, edema, cataracts, vomiting, thrombophlebitis.

Mitoxantrone
Most Common: cough or SOB, GI bleeding, leukopenia, stomach pain, stomatitis or mucositis.
Less Frequent or Rare: arrhythmias, CHF, conjunctivitis, jaundice, renal; failure, seizures, thrombocytopenia, allergic reaction, extravasation, local irritation, or phlebitis.

Anastrazole
Flushing, nausea, increased bone and/or tumor pain, breast pain, confusion, thrombophlebitis

Exemestane (Aromasin)
Hot flashes, nausea, fatigue, increased sweating, increased appetite, androgenic symptoms, peripheral edema

Megestrol Acetate
Most Common: breakthrough bleeding and anemorrhea, abdominal pain or cramping, edema, headache, mood changes, weight gain.
Less Frequent or rare: rash, depression, thromboembolism, breast pain or tenderness, hot flashes, insomnia, nausea.

Capecitabine
Nausea, vomiting, diarrhea, stomatitis, hand and foot syndrome, fatigue, parasthesias, anorexia, lymphopenia, neutropenia, thrombocytopenia, hyper bilirubinemia

Trastuzumab (Herceptin)
Parathesia, fever, chills, headache, CHF (more likely in combination therapy), nausea, vomiting, diarrhea, rash, peripheral edema

Epirubicin (Ellence)
Major Dose Limiting: Leukopenia, neutropenia
Hematologic: Leukopenia, neutropenia, anemia, febrile neutropenia
GI Effects: Nause, mucositis, diarrhea, anorexia, abdominal pain
Other: Alopecia, hot flashes, leukemia

Liposomal Ara-C (intrathecal) (DepoCyt)
Headache, arachnoiditis

Vinorelbine
Major Dose Limiting: Granulocytopenia, leukopenia
Hematologic: as above and anemia (mild)
GI Effects: nausea, vomiting, constipation, diarrhea, rise in total bilirubin, rise in SGOT
Nervous System Effects: peripheral neuropathy, asthenia
Other: injection site reactions, pain, phlebitis, alopecia, dyspnea

Paclitaxel
Most Common: hypersensitivity Rxns (less common with pre-medication), neutropenia, leukopenia, anemia, peripheral neuropathies, alkaline phosphatase elevation, alopecia, myalgia/anthralgia, radiation recall

Leuprolide
Hot Flashes, Nausea/Vomiting, Impotence, Loss of libido

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Pegfilgrastim *(PEG-fill-GRASS-tim)*

Brand Name: Neulasta® *(Noo-lasta)*

Patient Education Quick Reference Guide

Uses For This Medication

- Many chemotherapy medications reduce the number of germ fighting white blood cells, which increases the risk of infection. Pegfilgrastim helps to prevent this by increasing the number of white blood cells in patients who are receiving chemotherapy.
- This medication may also be given for other conditions as determined by your doctor.

How This Medication Works

Pegfilgrastim is known as a "colony stimulating factor" or "white blood cell growth factor". This medication is a man-made version of a substance that is naturally produced in your body which helps the bone marrow to make new white blood cells. Your doctor or healthcare provider may recommend that you have regular blood tests to count the number of white blood cells in your body. It is important that you follow your doctor or healthcare provider's instructions about these tests.

Benefits Of This Medication

Pegfilgrastim is given to prevent your white blood cell levels from becoming too low during chemotherapy treatment. This helps prevent the development of infections and helps to ensure that you will continue to receive your chemotherapy medications on time at the appropriate dose.

Who Should Not Take This Medication

You should not take this medication if you:

- Are allergic to other products made using a bacteria called *E coli*
- Are allergic to filgrastim, pegfilgrastim or any of its components

Precautions To Be Aware Of Before Taking This Medication

Allergy related precautions

The parent drug of pegfilgrastim is called filgrastim. Rarely, filgrastim may cause allergic reactions. These allergic reactions can cause rash, hives, shortness of breath, wheezing, a drop in blood pressure, swelling around the mouth or eyes, fast pulse, or sweating. Although allergic reactions have not been reported with pegfilgrastim, it is possible for them to occur. Your doctor or healthcare provider will watch you carefully during and after the administration of pegfilgrastim to make sure that you do not experience any allergic reactions. If you are receiving pegfilgrastim at home, you should tell your doctor or healthcare provider about any allergic type symptoms. If an allergic reaction occurs it is treatable with medications.

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Precautions (continued)

Blood related precautions

- The parent drug of pegfilgrastim is called filgrastim. Filgrastim has been reported to cause severe sickle cell crisis in patients who have sickle cell disease. If you have sickle cell disease, make sure that you tell your doctor or healthcare provider.
- Although pegfilgrastim can reduce the risk of infection, it may not prevent all infections. An infection can still happen when your white blood cell levels are low. You should watch for symptoms of an infection such as fever (temperature of 100.5 °F or higher), chills, sore throat, diarrhea, or redness, swelling, or pain around a cut. If you think you might have an infection, let your doctor or healthcare provider know immediately.

Organ related precautions

- The parent drug of pegfilgrastim is called filgrastim. Filgrastim has been reported to cause acute respiratory distress syndrome (ARDS). This is a life-threatening condition in which swelling and fluid build up in the lungs and leads to low oxygen levels in the blood. If you develop difficulty breathing, you should let your doctor or healthcare provider know immediately.
- The parent drug of pegfilgrastim is called filgrastim. Rarely, filgrastim has been reported to cause problems with your spleen (splenic rupture). Symptoms can include pain in the upper left portion of the abdomen or in the shoulder. Although a rupture of the spleen has not been reported with pegfilgrastim, it is possible for it to occur. Report any abdominal pain to your doctor or healthcare provider immediately.

Patient specific precautions

- It is not known if this medication is safe and effective in children.

Pregnancy and breastfeeding precautions

- ➢ When taking this medication, you should use effective birth control to prevent pregnancy. Tell your doctor or healthcare provider right away if you or your spouse/partner becomes pregnant since this medication may cause fetal harm.
- ➢ It is not known whether this medication is found or excreted in breast milk. Since many medications are excreted in breast milk and because this medication can cause serious harmful reactions in infants, breastfeeding should be avoided.

Administration related precautions

Pegfilgrastim should not be given during the time between 14 days before and 24 hours after chemotherapy, or while you are receiving radiation therapy.

Medication And Food Interactions

Before using this medication, tell your doctor or healthcare provider of all prescription or over-the-counter products you are taking, including dietary supplements or vitamins, herbal medicines and homeopathic remedies. Do not start or stop any medication without your doctor or healthcare provider's approval. Possible interactions can occur with pegfilgrastim and the following medications:

- Lithium

Side Effects

- All medications can cause side effects. However, not all patients will experience these side effects. In addition, other side effects not listed can also occur in some patients. You should call your doctor or healthcare provider if you have any questions or concerns while you are on this medication.
- You should contact your doctor or healthcare provider if you experience any side effect(s) which do not go away, worsen, are serious in nature, or are worrisome to you.

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Side Effects (continued)

More common side effects

- Bone and/or muscle pain [Acetaminophen (Tylenol) may be taken for pain relief (follow package directions)]
- Redness, swelling, or itching at site of injection

Rare side effects

- Allergic reaction which can cause rash, itching, red blotches, swollen face or lips, difficulty breathing (see Precautions To Be Aware Of Before Taking This Medication)
- Enlarged or ruptured spleen (see Precautions To Be Aware Of Before Taking This Medication)

How To Take This Medication

- This medication is usually given by an injection under the skin (subcutaneous or SC injection) but can also be given by injection into a vein (IV).
- If you or a family member are giving or receiving the pegfilgrastim injection at home, you should review the detailed information provided by the drug manufacturer on this subject. Read this information carefully and make sure that you understand how to prepare the injection, how to properly use the disposable syringes, and how to give the injection. If you have any questions about this information, check with your doctor or healthcare provider.
- When this medication is given as an injection under the skin (subcutaneous), there are four common areas where injections may be given:
  - The outer area of your upper arms
  - The abdomen, except for the two inch area around your navel
  - The front of your middle thighs
  - The upper outer areas of your buttocks

  It is best to rotate the areas where the injection is given to avoid soreness. It is best to avoid giving an injection in areas that are tender, red, bruised, hard, or that contain scars or stretch marks.
- In the unlikely event of an overdose of this medication contact your doctor, your local poison control center at 1-800-222-1222, or emergency services immediately.

Proper Storage

- Unopened containers should be stored in the refrigerator. Keep in original package to protect from light.
- Before being injected, pegfilgrastim may be allowed to reach room temperature for a maximum of 48 hours. During this time it should still remain in the original package protected from light.
- Keep the used syringes and needles in a special container.
- Keep this medication out of the reach of children or pets.
- Ask your doctor or healthcare provider how to dispose of any medication that you no longer use.

Disclaimer

This handout is to provide you with additional information about pegfilgrastim. It is not a substitute or replacement for the expertise and judgment of your healthcare provider. The information is not intended to cover all possible uses, directions, precautions, medication interactions, or side effects. In addition, this information should not be interpreted to suggest that the use of a particular medication is safe, appropriate, or effective for you. You should always talk with your healthcare provider before starting or stopping any medication.

Additional Instructions for Patient:

_____

_____

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ATTACHMENT C

University of California
San Francisco

School of Pharmacy
Office of the Dean

Mary Anne Koda-Kimble, PharmD
Professor and Dean
TJ Long Chair in
Chain Pharmacy Practice
521 Parnassus Avenue
Box 0622, Room C-156
San Francisco, CA 94143
tel: 415/476-8010
fax: 415/476-6632
kodakimblem@pharmacy.ucsf.edu
http://pharmacy.ucsf.edu

April 18, 2006

Ms. Patricia Harris, Executive Officer
State Board of Pharmacy
1625 North Market Blvd., N219
Sacramento, CA 95834

Dear Patty,

I am writing regarding the agenda item titled, "Request to Modify Intern Hours Earned for Pharmacy-Related Experience," a proposal to amend 16 CCR 1728. The UCSF School of Pharmacy opposes this proposal and appreciates the opportunity to convey our rationale.

I am familiar with the genesis of this proposal, since it is not the first time intern hours have been open to debate. In fact, I strongly supported a change in the regulation, which allowed students to receive credit for up to 600 hours of clinical clerkship experiences that were "substantially related to the practice of pharmacy," several decades ago. While I strongly encourage and promote student leadership initiatives and applaud the activism of our student groups, I differ with the views of students on this issue.

Currently, the Board of Pharmacy requires a total of 1500 Intern hours. Of these, 600 can be in a setting that is "substantially related to the practice of pharmacy"; the remaining 900 hours must be in a pharmacy under the supervision of a pharmacist. One of the stated reasons for the proposal (to allow up to 1000 hours of experience that is substantially related to the practice of pharmacy) is that it would provide students the opportunity to earn intern hours for new and innovative experiences that are not in a pharmacy. It has also been suggested that students do not pursue experiences in contemporary practices outside of licensed pharmacies because these do not qualify for intern hours required for licensure. We believe that the current regulation provides ample opportunity for students to pursue innovative experiences without jeopardizing their ability to complete the Board's requirement before graduation. We also believe that practice experience in a licensed pharmacy is absolutely essential to the development of a future pharmacist.

The UCSF School of Pharmacy curriculum currently includes *more than 1000 hours* of advanced pharmacy practice experience (clerkship) that would meet the Board's criteria for hours that are "substantially related to the practice of pharmacy." We assume the other California Schools of Pharmacy also meet or exceed this 1000 hour threshold. Therefore, the proposed change to 1000 intern hours "substantially related to the practice of pharmacy" would be entirely covered by the School's advanced pharmacy practice experiences. Consequently, the majority of students would simply be required to spend 400 fewer intern hours in a licensed pharmacy if this change is approved.

For more than 40 years the UCSF School of Pharmacy has designed and refined the educational experience it requires of students in the context of the Board of Pharmacy's requirement of 900 hours of practice experience in a pharmacy. This relationship has allowed the School to be creative in the types of practice experiences that are offered to our students since we know that an essential foundation for practice is provided through internship experiences in a pharmacy. A substantial change in the number of intern hours that are required in a licensed pharmacy (both institutional and community) will significantly disrupt the balance between the School's curricular experiences and the core skills and competencies students develop through their work as interns in licensed pharmacies. Our curriculum is predicated on this balance of experience and we believe the proposed change would not insure that our graduates have the core pharmacy skills and experiences we believe the public expects.

The UCSF School of Pharmacy has long embraced innovation in the profession and our new curricular pathways in *Pharmaceutical Health Policy & Management* and *Pharmaceutical Sciences* support our commitment to engaging students in new and expanding areas of practice. We also have mechanisms that allow individual students to substitute innovative practice experiences for some of their elective advanced pharmacy practice experiences. This process is evaluated by a faculty committee and allows for additional practice activities that are individualized, creative and innovative - though not yet mainstream.

Finally, the current requirement for 900 intern hours in a pharmacy under the supervision of a pharmacist can be met by one summer's full-time internship coupled with part time internship work during the student's academic year(s). We believe this allows most students at least one summer to explore outside professional activities that are professionally rewarding but do not meet the Schools' or Board's criteria for earning credit towards their academic degree and licensure.

The students' desire to expand the areas of practice experience and their focus on innovation – which are at the heart of this proposal – is to be commended. At the same time, we believe that the Board's requirement of 900 hours (less than one-half year) experience in a licensed pharmacy remains an essential component of the training and licensure of pharmacists who can best serve the public's needs. I also encourage the Board to once again adopt a statement of competencies to be gained from internship experiences in licensed pharmacies. Such a statement can be used to guide both students and preceptors in creating experiences that develop core competencies and skills the public deserves.

I am happy to discuss this in more detail with you and the Board.

Sincerely,

Mary Anne

Mary Anne Koda-Kimble, PharmD
Professor and Dean
TJ Long Chair in Chain Practice Pharmacy

ATTACHMENT D

Accreditation Commission for Health Care, Inc.

2006 MAR 15 PM 2:58

4700 Falls of the
Neuse Road,
Suite 280
Raleigh, NC 27609

(919) 785-1214
Fax (919) 785-3011
achc@achc.org
www.achc.org

March 13, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 N. Market, Suite N 219
Sacramento, CA 95834

Dear Ms. Harris,

I recently received a voice message indicating the need to submit our current pharmacy standards to the California State Board of Pharmacy. Enclosed is an updated program folder outlining the types of programs and process for companies accredited by the Accreditation Commission for Health Care (ACHC) and an Interpretive Guide to Standards for Accreditation for pharmacy services. Please note that all ACHC on-site surveys are done unannounced.

Since we recently have been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare, I have also enclosed a copy of the Federal Register announcing effective dates of this recognition for Medicare and Medicaid.

We appreciate this opportunity to continue our relationship with the California State Board of Pharmacy. If you have any questions, please contact me.

Sincerely,

Tom Cesar, MPM
President

THE PROVIDER'S CHOICE

ISO 9001:2000

[Federal Register: February 24, 2006 (Volume 71, Number 37)]
[Notices]
[Page 9564-9565]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr24fe06-90]

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[CMS-2227-FN]

Medicare and Medicaid Programs; Approval of Deeming Authority of the Accreditation Commission for Healthcare (ACHC) for Home Health Agencies

AGENCY: Centers for Medicare and Medicaid Services, HHS.

ACTION: Final notice.

SUMMARY: This notice announces our decision to approve the Accreditation Commission for Healthcare (ACHC) for recognition as a national accreditation program for home health agencies seeking to participate in the Medicare or Medicaid programs.

DATES: Effective Date: This final notice is effective February 24, 2006 through February 24, 2009.

FOR FURTHER INFORMATION CONTACT:
Cindy Melanson, (410) 786-0310.

SUPPLEMENTARY INFORMATION:

I. Background

policies; (2) financial and human resources available to accomplish the proposed surveys; (3) procedures for training, monitoring, and evaluation of its surveyors; (4) ability to investigate and respond appropriately to complaints against accredited facilities; and (5) survey review and decision-making process for accreditation.

A comparison of ACHC's HHA accreditation standards to our current Medicare HHA conditions for participation.

A documentation review of ACHC's survey processes to:

[boxvh] Determine the composition of the survey team, surveyor qualifications, and the ability of ACHC to provide continuing surveyor training.

[boxvh] Compare ACHC's processes to those of State survey agencies, including survey frequency, and the ability to investigate and respond appropriately to complaints against accredited facilities.

[boxvh] Evaluate ACHC's procedures for monitoring providers or suppliers found to be out of compliance with ACHC program requirements. The monitoring procedures are used only when the ACHC identifies noncompliance. If noncompliance is identified through validation reviews, the survey agency monitors corrections as specified at Sec. 488.7(d).

[boxvh] Assess ACHC's ability to report deficiencies to the surveyed facilities and respond to the facility's plan of correction in a timely manner.

[boxvh] Establish ACHC's ability to provide us with electronic data in ASCII-comparable code and reports necessary for effective validation and assessment of ACHC's survey process.

[boxvh] Determine the adequacy of staff and other resources.

[boxvh] Review ACHC's ability to provide adequate funding for performing required surveys.

[boxvh] Confirm ACHC's policies with respect to whether surveys are announced or unannounced.

[boxvh] Obtain ACHC's agreement to provide us with a copy of the most current accreditation survey together with any other information related to the survey as we may require, including corrective action plans.

In accordance with section 1865(b)(3)(A) of the Act, the September 23, 2005 proposed notice (70 FR 55862) also solicited public comments regarding whether ACHC's requirements met or exceeded the Medicare conditions of participation for HHAs. We received no public comments in response to our proposed notice.

IV. Provisions of the Final Notice

A. Differences Between the ACHC's Standards and Requirements for Accreditation and Medicare's Conditions and Survey Requirements

We compared the standards contained in ACHC's accreditation manual for

[[Page 9565]]

HHAs and its survey process in ACHC's Surveyor Training Manual with the Medicare HHA conditions for participation and our State Operations Manual. Our review and evaluation of ACHC's deeming application, which were conducted as described in section III of this final notice yielded the following:

To meet the full intent of all Medicare standards and conditions, ACHC crosswalked the corresponding Medicare standard to each of its standards and stated that HHAs undergoing a deemed status survey from ACHC would meet the ACHC standard as well as the

is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects; distributive impacts; and equity). The RFA requires agencies to analyze options for regulatory relief for small businesses. For purposes of the RFA, States and individuals are not considered small entities.

Also, section 1102(b) of the Act requires the Secretary to prepare a regulatory impact analysis for any notice that may have a significant impact on the operations of a substantial number of small rural hospitals. Such an analysis must conform to the provisions of section 604 of the RFA. For purposes of section 1102(b) of the Act, we consider a small rural hospital as a hospital that is located outside of a Metropolitan Statistical Area and has fewer than 100 beds.

This final notice recognizes ACHC as a national accreditation organization for HHAs that request participation in the Medicare program. There are neither significant costs nor savings for the program and administrative budgets of Medicare. Therefore, this final notice is not a major rule as defined in Title 5, United States Code, section 804(2) and is not an economically significant rule under Executive Order 12866. We have determined, and the Secretary certifies, that this final notice will not result in a significant impact on a substantial number of small entities and will not have a significant effect on the operations of a substantial number of small rural hospitals. Therefore, we are not preparing analyses for either the RFA or section 1102(b) of the Act.

In an effort to better assure the health, safety, and services of beneficiaries in HHAs already certified as well as provide relief to State budgets in this time of tight fiscal restraints, we deem HHAs accredited by ACHC as meeting our Medicare requirements. Thus, we continue our focus on assuring the health and safety of services by providers and suppliers already certified for participation in a cost-effective manner.

In accordance with the provisions of Executive Order 12866, this notice was not reviewed by the Office of Management and Budget. In accordance with Executive Order 13132, we have determined that this final notice will not significantly affect the rights of States, local or tribal governments.

Authority: Section 1865 of the Social Security Act (42 U.S.C. 1395bb)

(Catalog of Federal Domestic Assistance Program No. 93.778, Medical Assistance Program; No. 93.773 Medicare Hospital Insurance Program; and No. 93.774, Medicare--Supplemental Medical Insurance Program)

Dated: January 30, 2006.

Mark B. McClellan,

Administrator, Centers for Medicare & Medicaid Services.

[FR Doc. 06-1650 Filed 2-23-06; 8:45 am]

BILLING CODE 4120-01-P

N·H·I·A
NATIONAL HOME INFUSION ASSOCIATION

205 Daingerfield Road

Alexandria, VA 22314

Phone 703.549.3740

FAX 703.683.1484

www.nhianet.org

June 2000

To Whom It May Concern:

The National Home Infusion Association (NHIA) represents professionals and organizations providing home and alternate site infusion therapy services. An estimated 85 percent of NHIA members have successfully completed a process of voluntary accreditation for infusion therapy services or are planning to become accredited.

NHIA recognizes the importance of accreditation in setting a high standard of care for the infusion provider community. Currently, there are three accrediting organizations that have developed standards for infusion therapy and provide comprehensive accreditation services. These are:

- Accreditation Commission for Health Care (ACHC – www.achc.org)
- Community Health Accreditation Program (CHAP – www.chapinc.org)
- Joint Commission for Accreditation of Healthcare Organizations (JCAHO – www.jcaho.org)

NHIA strongly encourages the recognition of all three accrediting bodies where such accreditation is required for ancillary services contracts.

Sincerely,

Lorrie Kline Kaplan
Executive Director

Accreditation Commission for Health Care, Inc.

ACCREDITATION CROSSWALK OF HOME HEALTH STANDARDS Core: Sections 100 – 700

Note: Standard are cross-walked according to the intent of the standard and not according to the exact language of the standard. References to JCAHO standards are made to standards in the JCAHO manuals for home health services, home care pharmacy services, home medical equipment, respiratory therapy, and rehabilitation technology. CHAP standards are referenced to the Core standards only. ACHC standards are referenced to the Core and Home Health standards. The Scope of Service (clinical) standards portion of the cross-walk compare ACHC to JCAHO and the Medicare COPs.

DESCRIPTION OF STANDARD	ACHC	CHAP	JCAHO
Section 100 Organization and Administration			
Licensure, Incorporation documentation	101 A	E1.2A, C1.2a, C12a1	APR1
Change in Ownership or Management	101 B		APR2
Governing Body Duties defined	102 A	C1V.5A, E12B, C1V.5, C1V.5A, C12B3, C1V.4, C1.2b5, C1.2b6	LD.1.10, LD.1.20, LD.1.80
Description of Governing Body	102 B	C1.2b1	
List of Governing Body Members	102 C		
Governing Body Member orientation	102 D	C1.2b2	
Professional Advisory Functions	103 A	C1V.4G, C1V.7, C1V.7A	
List of Professional Advisory Members	103 B		
Professional Advisory Member orientation	103 C		
Advisory Committee meetings	103 D		
Written Policy for conflict of interest	104 A	C1.264d	RI.120
Share conflict of interest Policy	104 B	C1.2b4d	
Individual responsible for Operations	105 A	E1.3a, E1.3b, C1.3a	LD.2.20, LD.3.90
Annual written evaluation of Leader	105 B		
Appointed Leader replacement	105 C	C1.3d	LD.3.50, LD.4.10
Organization Chart	106 A	C1V.3G, C12E1, C11.3a	
Supervision of each Service	106 B	C1.3e, C1V.3G	LD.3.40, LD.3.70, R.1.10
Personnel knowledge of chain of command	106 C	C1.2C2, C1V.3G	
Written Mission and Philosophy statement	107 A	E1.1, C1.1, C1B1, C1.4F, C1.1b, E1.1	
Organizational Goal identified	107 B	C1B.1, C1V.1B	
Compliance with laws and regulations	108 A	E1.2A, E11.7C, C1.2a, E11.3b(1)(0)	LD.1.30, LD.3.20
Reports of negative reviews/audits	108 B	E1.2B	
Section 200 Program/Service Operations			
Descriptions of service/care	201 A	C1.4a, E11.2C, E11.2d(d), C1.4b	RI.1.10
Staff knowledge of Descriptions	201 B		
Description give to Client and Family	201 C		

Accreditation Commission for Health Care, Inc.

DESCRIPTION OF STANDARD	ACHC	CHAP	JCAHO
Bill of Rights distributed to Patients	202 A	C1.4a	RI.2.10, RI.2.20, RI.2.30, RI.2.40, RI.2.50, RI.2.60, RI.2.70, RI.2.80, RI.2.90, RI.2.100, RI.2.110, RI.2.120, RI.2.130, RI.2.140, RI.2.150, RI.2.160, RI.2.180, RI.3.10,
Staff trained on Bill of Rights and Responsibility Policy	202 B		
Distribution of Bill of Rights and Responsibility Statement	202 C	C1.4c	
DMEPOS Standards and Medicare Recipients	202 D		
Client Grievance Process Review	203 A	C1.d	
Staff Grievance Process Review	203 B		
Grievance Process Investigation	203 C		
Client Grievance Process Contact Information	203 D		
Confidentiality Policies and Procedures	204 A	CIV.5B	
Personnel, Governing Body and Advisory knowledgeable of Confidentiality	204 B		
Client receipt of Confidentiality information	204 C		
Business Associate Contracts	204 D		
Client right to refuse service, set Advance Care Directives	205 A		
Documentation of receipt of Advance Care Directives	205 B		
Resuscitative Guidelines	205 C		
Process for Suspected Abuse/Neglect	206 A		PC.3.10, RI.2.150
Staff Knowledge of Reporting Suspected Abuse	206 B		
Reporting Suspected Abuse to Authorities	206 C		
Written Policies on Ethical Issues	207 A	C1.4g, C1.4g1b, C1.4g1, C1.4g1c, C1.4g3, C11.1a	RI.1.10
Staff Knowledge of Reporting Ethical Concerns	207 B		
Reporting Ethical Concerns to Governing Body	207 C	C1.4g1a	
Policies Addressing Various Cultures, Beliefs, and Languages	208 A		
Staff Knowledgeable of Diversity	208 B		
Staff Communication mechanisms	208 C		
Compliance Program	209 A	C111.2H	
Section 300: Fiscal Management			
Budgeting Process Policy	301 A	E1.4A, C111.2E1, C111.2E4, C111.2, C111.2b, C111.2a	LD.2.50
Review of Annual Budget	301 B	C111.2E4, C111.2F3, C111.2E3, C111.2C, C111.2E2	
Written Capital Expenditure Plan	301 C	C111.2E5, C111.2, C111.2C, C111.2B	

Accreditation Commission for Health Care, Inc.

DESCRIPTION OF STANDARD	ACHC	CHAP	JCAHO
Expenditure Limits	301 D	C111.2E5	
Policies for sound business practices	302 A	E11.2d(d), C1V.5C, C1V.201, C111.2G2, C111.2C, C1V.3E, C1V.3F, C111.2F, C1V.1C	
Accounting System	302 B	E111.2a, C1V.3F, C111.2C, C111.2F, C111.2d, C111.2F1	
Fiscal Policies for OASIS data	302 C		
Financial Record Retention	303 A	C1.2B, C111.2F2	
Financial Quarterly Review	303 B	C1V.5d, C111.2H1	
Communication of Service/Care Rates	304 A	C1V.2E, C1V.2F, C1V.3, C111.2G1, C111.2F2, C111.2F4, C111.2F5	
Staff trained in Rates Policy	304 B	C1V.2D, C1V.3D	
Provide Client with Rates prior to service	304 C	E11.2d(i), C1V.3E	
Criteria for sliding fee scale	304 D		
Section 400 Personnel Management			
Personnel Policy Management and Review	401 A	C111.1F, C111.1F1	
Policy accessibility to Staff	401 B	C111.1F2	
Job Descriptions consistent with Organization Chart	402 A	E11.1b(d), E111.1e2(d), C1.3a, C11.1b	
Employee receipt of Job Description	402 B	E11.1b(i), E11.1e2(i)	
Policy for Verification of Employee Qualifications	403 A	E111.1b2, E111.1b1, E111.1e2(d), C1.3e, C11.1a, C11.1b	
Qualifications Verified	403 B	C111.1g2	
Personnel Credentialing Activities	403 C	E111.1b1, C111.1g2, C11.1a	HR.1.20
TB Screening or Verification	404 A	C11.7b3,	
Hepatitis B Vaccination access	404 B	C11.7b2	
Driver's License Requirements	404 C	E111.1b3, E111.3b1	
Vehicle Insurance	404 D		
Criminal Record Background Check	404 E	C111.1g2	
Management of Personnel Files	405 A	C1.2g, C11.7c, C111.1g, C111.1g1 C111.1g2	
Written Orientation Plan	406 A	E111.1b4, C111.1C, C111.1I, C111.1H	HR.2.10
Orientation Personnel Training	406 B		
Staff Participation in Orientation	406 C		HR.2.20
Staff Performance Competency	407 A	E11.1b(o), E11.1e2(o), E111.1f(i), C111.1G2	HR.2.30, HR.3.10
Demonstration of Competency on new tasks	407 B	E11.1b(i)	

Accreditation Commission for Health Care, Inc.

DESCRIPTION OF STANDARD	ACHC	CHAP	JCAHO
In-Service Education	408 A	C111.1G2, C111.1I, C111.1J2, C111.1I3	
Policies pertaining to Supervision	409 A		
Qualifications Appropriate to Service/Care	409 B		
Supervision Available during all Service Hours	409 C		
Annual Observation of Direct Service Staff	410 A	C111.1G2, C1V.5F,	
Written Annual Performance Evaluations	410 B	C1V.5F, C111.1G2, C111.1e1, C111.1h	HR.3.10, HR.3.20
Results of Performance Evaluations	410 C	C111.1e2	
Negative Patient Outcome Actions	410 D		
Written Contracts/Agreements	411 A	C1V.6A, E111.1J2, E111.1c, C111.1J	
Review of new Contracts and Renewals	411 B	E11.2e(d), C111.1J4	
Professional Liability Insurance	411 C	C111.1G2	
Contract Requirements	411 D	C111.1J1, C111.1J3	
Monitoring of Contract Providers	411 E	C111.1J1	
Section 500 Client/Patient Record Management			
Required Content Policies	501 A	E11.4c1(d), E11.4d(d), E11.5c, C11.5, C11.5F	IM.2.30
Access, Storage, Removal and Retention Policies	501 B	C11.5a, C11.5b, C11.5e2, C11.5d C11.5e,	IM.2.10, IM.2.20, I.3, I.3.10
Record for each Client	501 C	E11.5c(d), E11.5a, C11.i, C11.5e, C11.5g	IM.6.10
Record Documentation	501 D	C11.5e, C11.5e1	IM.6.60
Demonstrated Consistency; Service, Plan and Billing	501 E	E11.4d(d),C1V.4d	IM.6.20
Referral Process Description	502 A		
Service Guidelines and Eligibility	502 B		RI.1.30, IM.4.
Anti-Discrimination Compliance	502 C		RI.1.30, LD.3.20
Verification of Physician Credentials	502 D		PC.1.10
Verification of Client Eligibility	502 E		
Referrals for Unmeetable Needs	503 A	E11.1e1 (o), C1.4c1, E11.2b(d, i)	RI.1.40, IM.1.10
Service Availability in Community	503 B	E1V.2	
Section 600 Quality Outcomes Management			
Designation of Quality Outcomes/Improvement Coordinator	601 A		LD.14.40
Involvement of Leadership in QI	601 B	E1V.1b, C11.6a1, C11.6h	
Involvement of Staff in QI	601 C	C11.1b, C11.6a1, C1V.1d, C111.1e	
Annual Evaluation of QI	602 A	E1V.1a, C11.4, C1B.1, C11.6, C11.6a, C1V.2, C1V.2a, C111.1d ,C1V.2b, C1V.2c1, C111.1F, C1V.1a	PI.1.10

Accreditation Commission for Health Care, Inc.

DESCRIPTION OF STANDARD	ACHC	CHAP	JCAHO
Assessment of Processes Involving Risk	602 B	C11.6b, C11.6c includes B, C, D, E, F, + 603 A, B, C	RI.2.30
Ongoing Monitoring of Important Service/Care Aspect	602 C	C1V.2C2	
Ongoing Monitoring of Administrative Aspect	602 D		
Satisfaction Surveys	602 E	C11.1b, C11.6c1, C111.6F	
Review of Client Records	602 F	E11.2A(i) C11.6F2	
Quality Improvement Requirements	603 A	C11.6e	PI.2.10, PI.2.20
Participation in External Benchmarking	603 B	C1V.5E	
Annual Quality Improvement Report	603 C	C1V.2c2	
Written Plan of Correction	604 A	C1V.2c3, C11.6s, C1V.2c2	LD.4.50, PI.3.10
Plan of Correction Outcomes	604 B	C1V.2c2, C1V.2c3, C11.6g	
Investigation of all Adverse Events	604 C		PI.1.10, PI.1.220, PI.2.230, PI.3.10, PI.3.20
Section 700 Risk Management			
Infection Control Policies	701 A	E11.7, C11.7b2, C11.7b3, C11.7, C11.7a, C11.7a1, C11.7b	IC.1.10, IC.9.10
Infection Control Education	701 B	C11.7b5, C11.7b6	IC.8.10
Demonstration of Compliance	701 C	E11.7a	IC.2.10, IC.7.10
Evaluation of Effectiveness	701 D	C11.7b4, C11.7e, C11.7e1, C11.7F	IC.6.10, IC.3.10, LD.4.70
Safety Issue Education	702 B	C11.7h	IC.5.10, EC.7.30
Disaster Preparedness Plan	703 A	C11.8, C11.1c	EC.4.20
Disaster Preparedness Education of Staff	703 B	C11.1c, C11.8	EC.7.10, EC.7.40, EC.9.10, EC.9.20, EC.9.30,
Assessment of Utility Systems	704 A		
Fire Safety and Emergency Power Plans	705 A	C111.13A	EC.2.10, EC.1.3, EC.8.10
Fire Safety and Emergency Power Plan Implementation	705 B	C111.13A	EC.5.10, EC.5.20, EC.5.30, EC.5.40
Hazardous Chemical Plan	706 A	C11.7b1b	
OSHA Hazard Communication Standard Compliance	706 B	C11.7b1c	EC.3.10
Variance Plan	707 A	C11.7d1	
Variance Education	707 B	C11.7d2	
Variance Documentation and Reports	707 C	C11.7d, C11.7e, C11.3c	
Certificate of Waiver from DHH	708 A		
Utilization Purposes and Staff Training	708 B		
Equipment Utilized in Waived Tests	708 C		

ATTACHMENT E

CHAP

Community Health Accreditation Program, Inc.
1300 19th Street NW, Suite 150 Washington, DC 20036 t: 202-862-3413 f: 202- 862-3419 web: www.chapinc.org

2006 MAR 15 AM 10: 23
BOARD OF PHARMACY

March 14, 2006

Patricia Harris
Executive Officer
California State Board of Pharmacy
1625 N. Market, Suite N219
Sacramento, CA 95834

RE: Re-Application for Board Approval under Senate Bill 293, Section 4127.1d

Dear Ms. Harris:

The Community Health Accreditation Program, Inc. (CHAP) is re-applying to California State Board of Pharmacy for approval to exempt pharmacies from licensure under requirements established by Senate Bill 293, Section 4127.1d of the Business and Professional Code.

Included is CHAP's current response to the evaluation factors identified by the Licensing Committee as required in section 4127.1. CHAP supportive documentation is attached as Appendix I-III. Included also is a cross-walk from CCR Section 1751 (revised) Sterile Compounding Regulations to CHAP CORE Standards 2004 and CHAP Pharmacy Standards 2004/1005.

Thank you for consideration of this re-application.

Please contact me if you need further documentation.

Sincerely yours,

Terry A. Duncombe, RN, MSHA
President & CEO

RE-APPLICATION TO THE CALIFORNIA STATE BOARD OF PHARMACY FOR APPROVAL TO EXEMPT PHARMACIES FROM LICENSURE UNDER REQUIREMENT ESTABLISHED BY TITLE 16 CALIFORNIA CODE OF REGULATIONS SECTION 1751 – REVISED (SECTION 4127, 4127.7 OF THE BUSINESS AND PROFESSIONS CODE)

SUBMITTED BY:
COMMUNITY HEALTH ACCREDITATION PROGRAM, INC. (CHAP)
1300 19th Street, Suite 150
Washington, DC 20036

Factor 1. Periodic Inspection

The Community Health Accreditation Program, Inc. (CHAP) conducts a full comprehensive site visit to pharmacies at least once every three years. Every standard for Core and Pharmacy, is assessed during these site visits. Based upon the performance of the pharmacy and the findings, particularly in the Quality Standards (Section II of each set of standards), the CHAP Board of Review may determine to require a return site visit within 6 -12 months to focus on and assess compliance with the required actions cited during the site visit. The Accreditation Process is described in the CHAP informational brochure, which is included as Appendix I.

Factor 2. Documented Accreditation Standards

CHAP accredits all types of pharmacies, including pharmacies that compound sterile products. CHAP currently uses two sets of standards to assess pharmacy services: Core 2004 (overall administrative standards) and Pharmacy 2004/2005 (service specific standards) Standards of Excellence. The Standards are included as Appendix II. Each of the standards contain language further requiring compliance with State and Federal statues governing pharmaceutical practice. Each pharmacy is assessed during a site visit for compliance with CHAP standards as well as federal and state-specific regulations. In addition, CHAP standards are consistent with the professional standards of practice as defined by the American Society of Health System Pharmacy and published in Best Practices for Health-System Pharmacy, ASHP, and referenced for assessment.

Subsequent to CHAP's initial application to the California State Board of Pharmacy in 2003, CHAP revised its pharmacy standards and formatted them in a tiered structure with basic standards applicable to all pharmacy services plus add-on standards with additional requirements applicable to specialized pharmacies such as infusion pharmacies. The CHAP 2004/2005 Pharmacy Standards are consistent with the intent of USP 797, incorporate requirements from Medicare Modernization Act, Part D, and are consistent with California State Board of Pharmacy Sterile Compounding Special Licensure regulations.

CHAP assesses standards in terms of "Met" or "Not Met." The standard must be met in full to be assessed as "Met." If any element of the standard is not met, the standard is assessed as "Not Met," and a "Required Action" is written for that Standard. Required Actions are actions which the organization is required to perform in order to achieve compliance with CHAP Standards. The Board of Review decision to accredit, deny accreditation or defer accreditation is based upon the number and types of Required Actions identified. CHAP does not use a scoring methodology for assessing compliance and determining accreditation decisions

An organization is **accredited** if the site survey findings provide evidence that the organization is in substantial compliance with CHAP standards. An organization is **deferred** in initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards but has evidence that they possess the ability to come into substantial compliance within a reasonable time frame, not to exceed one year from the deferral date. A full site visit will subsequently be conducted to determine compliance with CHAP standards. An organization is **denied** initial accreditation based upon evidence that the organization is not in substantial compliance with the CHAP Standards and lacks adequate structure and function to correct the deficiencies in a timely manner. The organization has the option of re-initiating the application process six months from the date of the initial site visit. Other Board of Review accreditation decisions include **formal warning** and **termination.**

Factor 3. Evaluation of Surveyor's Qualifications.

CHAP requires pharmacy site visitors to have the following minimum qualifications:

1. Currently licensed Registered Pharmacist with a minimum Bachelor of science in pharmacy.
2. Five years experience in pharmacy management.
3. Current experience in community-based or infusion-based compounding pharmacy services.
4. Demonstration of strong analytical, consultative, conflict resolution, mediation and written and written and verbal articulation skills.
5.. Demonstration of experience with an accreditation process.
6. Successful completion of a CHAP Site Visitor Training Program and four practicum site visits.

CHAP currently has four pharmacy site visitors with professional pharmacy experience ranging from 12 – 40 years, with clinical management experience ranging from 9 – 30 years, with one holding a Masters degree and two holding Doctor of Pharmacy degrees. Each one of CHAP's pharmacists is currently employed in active pharmacy services.

The CHAP Board of Review (BOR) has a pharmacist position appointed by the Board of Directors. That pharmacist is responsible for reviewing and assessing Pharmacy Site Visit Reports to assure consistent citation of pharmacy standards. The BOR Pharmacist is also responsible for assessing new or revised standards as part of the BOR and recommending adoption to the Board of Directors.
The CHAP Board of Directors (BOD) has a pharmacist member elected by the Board of Directors who is also a resource for pharmacy-industry related issues.

Factor 4. Acceptance by Major California Payors

CHAP is accepted by all California payors as well as all national payors.

Factor 5. Unannounced Inspection of California Accredited Sites

CHAP understands that the State Board of Pharmacy will conduct unannounced inspections of two or more California accredited pharmacy sites to assess for satisfactory compliance with California law and good professional practice.

Factor 6. Board Access to Accreditor's Report on Individual Pharmacies

CHAP provides a written report to each pharmacy following a site visit and review and determination by the Board of Review. Each of the pharmacies accredited by CHAP has a copy of the written report available on site.

Factor 7. Length of Time the Accrediting Organization Has Been Operating

CHAP has been accrediting organizations since 1965. CHAP was the first national accreditation organization to accredit community-based health organizations in the United States and was the first organization awarded deeming authority by CMS (formerly HCFA) for home health in 1992 and for hospice in 1999. CHAP Pharmacy Standards are recognized by JCAHO as being comparable in definition and expectations.

Factor 8. Ability to Accredit Out-of-State Pharmacies.

CHAP currently accredits organizations throughout the United States, Hawaii and Puerto Rico and is able to accredit pharmacies regardless of state of operation.

CHAP currently accredits 63 Pharmacies located in 23 states. CHAP has 16 pharmacies that have applied for accreditation and are in the process of contract execution or currently undergoing the self-study process.

Additional Questions:

1. What companies are accredited for Pharmacy by CHAP in California?

Accredited:
Factor Support Network Pharmacy, Inc., Camarillo

Applied for Accreditation:
Valu-Med Pharmacy, Anaheim
Pharmaco d/b/a Premier Infusion Care, Torrance

2. Is CHAP accreditation comparable to JCAHO ?

JCAHO has completed an evaluation of CHAP standards which resulted in their recognition of general comparability between the standards of our two organizations.

3. What is an example of an evaluation sheet and report?

The CHAP Site Visitor Work Book is used for evaluating compliance with the CHAP Standards. A Board of Review Site Visit Report is generated from the commendations, recommendations and required actions cited in the Site Visitor Work Book. The Board of Review reviews the Site Visit Report and completes a Summary Data Collection Tool in order to assure a logical and focused review of Site Visit Reports and to promote consistency in the interpretation of site visit findings by each reviewer. Consistency in the interpretation of site visit findings by the Board of Review drives the decision making process. A sample of the Site Visitor Work Book, the Board of Review Site Visit Report format and the Board of Review Summary Data Collection Tool are included as Appendix III.

COMMUNITY HEALTH ACCREDITATION PROGRAM, INC.
CROSSWALK OF CHAP PHARMACY STANDARDS 2004/2005 EDITION TO CALIFORNIA CODE OF REGUALATIONS
TITLE 16, SECTION 1751 (REVISED) and SECTIONS 4127, 4127.7
STERILE COMPOUNDING SELF-ASSESSMENT

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751: COMPOUNDING AREA	
Clean room with walls, ceilings & floors are made of non-porous cleanable surfaces.	DIII.4a.3
Well ventilated.	DII.8a.6,8, DIII.4a.5
Laminar air flow hoods & clean room equipment are certified annually.	DIII.4f
Supplies stored in a manner which maintains integrity of an aseptic environment.	DIII.4a.7a DIII.4a.7c
There is a sink with hot and cold running water.	DIII.4a.2
There is a refrigerator of sufficient capacity to meet the storage requirements for all material requiring refrigeration.	DIII.4a.7b
CCR 1751.01: FACILITY AND EQUIPMENT STANDARDS FOR STERILE INJECTABLE COMPOUNDING FROM NON-STERILE INGREDIENTS	DIII.4a, DIII.4b.1
On or after July 1, 2005, the following shall apply to any pharmacy compounding sterile injectable products from one or more non-sterile ingredients.	
A ISO class 5 (class 100) laminar flow hood within an ISO class 7 (class 10,000) clean room (with positive air pressure differential relative to adjacent areas)	DIII.4a, DIII.4b.1
OR	
A ISO class 5 (class 100) clean room with positive air pressure differential relative to adjacent areas	DIII.4a, DIII.4b.1
OR	
A barrier isolator that provides a ISO class 5 (class 100) environment for compounding	DIII.4a, DIII.4a.1, DIII.4b.1, DIII.4e
No sterile injectable product prepared if it is known or reasonably should have known that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe, compounding of sterile injectable drug products.	DII.7c.2, DII.8f.5, DIII.4b.5, DIII.4e, DIII.4g
Access to designated area or clean room limited to those individuals who are properly attired.	DII.8a.4, DII.8f.2, DIII.4g
All equipment used in the designated area or clean room must be made of a material that can be easily cleaned and disinfected.	DII.4a.3, DII.4a.7c, DII.8a.7
Exterior workbench surfaces and other hard surfaces in the designated area such as walls, floors, ceilings, shelves, tables and stools must be disinfected weekly and after any unanticipated even that could increase risk of contamination.	DII.7c.2, DII.8f1, DIII.4b2

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751.02: POLICIES AND PROCEDURES	
Written policies and procedures associated with the pharmacy's preparation and dispensing of sterile injectable products shall include but not be limited to:	DI.5
• Compounding, filling, and labeling of sterile injectable compounds	DI.5c.13, DI.5c.18-21
• Labeling of the sterile injectable product based on the intended route of administration and recommended rate of administration.	DII.5e.10, 11
• Equipment and supplies	DI.5c.14, 15
• Training of staff in the preparation of sterile injectable products	CI.5d.5, DI.5c.22-23, DII.8d
• Quality Assurance Program	DI.5e
• Record keeping requirements	CI.5c.9, CI.5h, CII.5a-g, DI.5c.17, DII.2b1f.1-7, DII.6a-b
• The ingredients and the compounding process for each preparation must be determined in writing before compounding begins and must be reviewed by a pharmacist	DII.2b1a4, DII.5c, DII.5d.2, DII.8f.3,4
• Written policies and procedures immediately available to all personnel involved in the compounding activities and Board of Pharmacy Inspectors	CI.5i, CIII.1f
• All personnel involved must read the policies and procedures before compounding sterile injectable products and any additions, deletions, and revisions to the written policies and procedures must be communicated to all personnel involved in sterile compounding	CI.5g.9a-c, CI.5i
Policies and procedures must address at least the following:	
• Staff competency evaluations	CIII.1i, DI.5c.22.23, DII.8f5, DIII.1c,1d
• Storage and handling of products and supplies	DI.5c1,3,9
• Storage and delivery of final product	DI.5c1,7,18, DIII.4c
• Process validation	DI.5c18, DII.7c2, DII.8f
• Personnel access and movement of materials into and near the compounding area	DII.8f2, DII.8a.1-10
• Use and maintenance of environmental control devices used to create the critical area for manipulation of sterile products (e.g. laminar air flow workstations, biological safety cabinet, class 100 clean room, and barrier isolation workstations).	DI.5e, DI.5c15, DII.8e

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
• Regular cleaning schedule for the controlled area and any equipment in the controlled area and the alternation of disinfectants (pharmacies subject to institutional infection control policy may follow that policy).	DI.5c.15, DII.8a.7, DII.8f
• Disposal of packaging materials, used syringes, containers, and needles to enhance sanitation and avoid accumulation in the controlled area.	DI.5e4, DII.8a9,10, DII.8c
• For sterile batch compounding, written policies and procedures must be established for the use of master formulas and work sheets and for appropriate documentation.	DII.6a.2,3
• Sterilization procedures exist (including documentation of sterilization results).	DI.5c18
• End-product evaluation and testing occurs.	DII.7c2, DIII.4b5
CCR 1751.2: LABELING REQUIREMENTS	
Labels to include telephone number of pharmacy (exemption: sterile injectable products dispensed for inpatients of a hospital)	DII.5e1
Name and concentration of ingredients contained in the product	DII.5e6
Instructions for storage and handling	DII.5e7, DIII.8d1-3
All cytotoxic agents shall bear a special label which states "Chemotherapy-Dispose of Properly"	DII.5e9
CCR 1751.3: RECORD KEEPING REQUIREMENTS	DII.6
There is an immediately retrievable patient medication profile for each patient.	DII.6
Pharmacies compounding sterile injectable products for future use shall also have records indicating the name, lot number, amount, and date on which the products were provided to the prescriber.	DII.5e, DII.6a2,3
Maintenance of records for three years to include:	CI.5h2,3
• Training and competency evaluation of employees in sterile product procedures.	CI.5h8, CIII.1g13
• Refrigerator and freezer temperatures are monitored and documented.	DII.4a,b,c
• Certification of the sterile compounding environment occurs on a regularly scheduled basis according to written policies and procedures.	DII.6a3d, DIII.4b4, DIII.4f
• Other facility quality control logs specific to the pharmacy's polices and procedures are maintained (e.g. cleaning logs for facilities and equipment)	DIII.4b1-5
• Inspection records for expired or recalled pharmaceutical products or raw ingredients exists.	DI.5c25, DII.8c1
• Preparation records including the master work sheet, the preparation work sheet and records of end-product evaluation	DII.6a3d, DII.4a-c, DII.7c2, DIII.4b5

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
CCR 1751.4 ATTIRE	
When preparing cytotoxic agents, gowns and gloves are worn	DII.8a.4
Clean room garb consists of a low-shedding coverall, head cover, face mask, and shoe covers must be worn inside the designated area at all times.	DI.5e, DI.5e.4
Clean room garb must be donned and removed outside the designated area	DI.5e, DI.5e.4
Hand, finger and wrist jewelry must be removed. If jewelry cannot be removed, the jewelry must be thoroughly cleaned and covered with a sterile glove	DI.5e, DI.5e.4
Head and facial hair must be kept out of the critical area or be covered	DI.5e, DI.5e.4
Protective gloves made of low-shedding materials are required	DI.5e, DI.5e.4
Note: Requirements may not apply if a barrier isolator is used to compound sterile injectable products from one or more non-sterile ingredients.	
CCR 1751.5: TRAINING OF STAFF, PATIENT AND CAREGIVER	
Consultation shall be available to the patient and/or primary caregiver concerning proper use of sterile injectable products and related supplies furnished by the pharmacy	DII.5i, DII.5j, DII.8d
The pharmacist-in-charge shall ensure all personnel engaged in compounding sterile injectable drug products shall have training and demonstrate on-going competence in the safe handling and compounding of sterile injectable drug products including cytotoxic agents.	CIII.1l, DIII.1c, DIII.1d, DIII.1g
Records of training and demonstrated competence shall be available for each individual and shall be retained for 3 years beyond the period of employment.	CI.5h.8
Pharmacies must have an established and follow a written program of training performance evaluation designed to ensure that each person working in the designated area has the knowledge and skills necessary to perform their assigned tasks properly.	DIII.1g
The program of training and evaluation shall address the following: aseptic technique, pharmaceutical calculations/terminology, sterile products compounding documentation, quality assurance procedures, aseptic preparation procedures, proper gowning and gloving techniques, general conduct in the controlled area, cleaning/sanitizing and maintaining equipment used in the controlled area, sterilization techniques, container, equipment and closure system selection.	DII.8f, DIII.1b10, DIII.1c, DIII.1d

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CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
Each person assigned to the controlled area must successfully complete practical skills training in aseptic technique and aseptic area practices.	DII.8a, DIII.1b.6,10, DIII.1g
Evaluations must include written testing and a written protocol of periodic routine performance checks involving adherence to aseptic area policies and procedures.	DIII.1d.1-5
Each person's proficiency and continuing training needs must be reassessed every 12 months.	DIII.1c.2, DIII.1d
Results of staff assessments must be documented and retained in the pharmacy for three years.	CIII.1g.8,9, CIII.1i.1-4
CCR 1751.6: DISPOSAL OF WASTE MATERIAL	
Pharmacies compounding sterile injectable products shall have written policies and procedures for the disposal of infectious materials and/or other materials containing cytotoxic residue.	CII.7e.4, CII.7e.5, DI.5e.4, DII.8a.10
Procedures shall include cleanup of spills and shall be in conformance with local health jurisdiction.	DII.8c.2, DIII.4a
CCR 1751.7: QUALITY ASSURANCE AND PROCESS VALIDATION	
Each pharmacy shall have a documented on-going quality assurance program that monitors personnel performance, equipment, & facilities.	DII.5e, DII.7, DII.8a.1-10, DII.8c, DII.8f
The end product shall be examined on a periodic sampling basis as determined by the pharmacist-in-charge to assure that the product meets required specifications.	DI.5c.18, DII.7c, DIII.4b.5
The quality assurance program shall include:	
• Cleaning & sanitization of the parenteral medication preparation area.	DII.8a7, DII.8d.1, DIII.1f.1-5, DIII.4b.1-5
• Written documentation that the end product has been tested on a periodic sampling basis for microbial contamination & steps taken in the event that testing for contamination proves positive.	DII.7b, DII.7c.2, DIII.4b.5
• The storage of compounded parenteral products in the pharmacy and periodic documentation of refrigerator temperature.	DIII.4c, DII.8d.2
• Steps taken in the event of a drug recall.	DI.5c.25, DII.8c.1
• Written justification of the chosen expiration date for compounded injectable drug products.	DII.5e.11
Process Validation:	
• Each individual involved in the preparation of sterile injectable products from one or more non-sterile ingredients must successfully complete a validation process before being allowed to prepare sterile products.	DII.8f.2,4,5, DIII.1b.10, DIII.1d.1-5, DIII.1c

CALIFORNIA CODE OF REGULATIONS SELF-ASSESSMENT DESCRIPTION *Title 16, Section 1751 (Revised)*	**CHAP STANDARD**
• The validation process shall be carried out in the same manner as normal production, except that an appropriate microbiological growth medium is used to test the sterility of the final product.	DII.8f.5, DIII.4e.1
• The same personnel, procedures, equipment, and materials are involved.	CIII.1i.1-4, DII.8f.1-5
• Completed medium samples must be incubated.	DIII.7c.2, DII.8f.5
• If microbial growth is detected, then the sterile preparation process must be evaluated, corrective action taken, and the validation process repeated.	CII.6d, CII.6e, CII.6g, DII.7c.2
• Personnel competency must be revalidated at leaset every 12 months, whenever the quality assurance program yields an unacceptable result, or whenever improper aseptic techniques are observed.	DIII.1d.1-5
• The validation and revalidation process must be documented.	CIII.1g.8a-b,15, CIII.1i.4, DII.6a.3d
CCR 1751.9: REFERENCE MATERIALS	
There must be current and appropriate reference materials regarding the compounding of sterile injectable products located in or immediately available to the pharmacy.	DI.2d, DIII.1g

ATTACHMENT F

March 8, 2006

Patricia F. Harris
Executive Director
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Dear Ms. Harris,

We would like to request the opportunity to discuss an extension of the waiver for the study by the UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting," at the March 22, 2006 Licensing Committee Meeting. The two-year study was approved by the State Board of Pharmacy on April 21, 2004 . After the Board of Pharmacy's approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Medical Center and the Committee on Human Research at UCSF. Therefore, in order to complete the data collection, analysis and review of the results, we would like to request an extension until December 31, 2006. Please free to contact me should you have any questions. Thank you for your consideration.

Sincerely,

Peter J. Ambrose, Pharm.D., FASHP
Professor of Clinical Pharmacy
UCSF School of Pharmacy
C-152, Box 0622
San Francisco, CA 94143-0622
Long Beach Office: 562-933-0289

Rita Shane, Pharm.D., FASHP
Director, Pharmacy Services
Cedars-Sinai Medical Center
Assistant Dean, Clinical Pharmacy
UCSF School of Pharmacy
Los Angeles, CA
310-423-5611
shane@cshs.org

cc: Frank Saya, Pharm.D.

UCSF
University of California
San Francisco

BOARD OF PHARMACY
2006 APR -7 PM 2:58

LA/OC Area Clerkship Program
Department of
Pharmacy Services
Long Beach Memorial
Medical Center
2801 Atlantic Avenue
P.O. Box 1428
Long Beach, CA 90801-1428
tel: 562/933-0289
fax: 562/933-2348

April 5, 2006

Patricia F. Harris
Executive Director
California State Board of Pharmacy
1625 North Market Blvd, Suite N219
Sacramento, CA 95834

Re: Technician Study –Second Interim Report

Dear Ms. Harris:

As per the waiver approved by the Board of Pharmacy, I am submitting the second interim report of the study conducted at Cedars-Sinai Medical Center: **Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting.** The attached document summarizes the results for the first 80 weeks of the two-year study, which I plan to present at the Board meeting on April 26 in Sacramento. Dr. Rita Shane will also be available at the upcoming meeting to answer any questions.

The results to date continue to demonstrate the positive impact on patient care and medication safety that can be achieved by creating time for pharmacists to interact with the nursing and medical staff rather than using pharmacists to perform the non-discretionary task of checking technician-filled unit-dose medication carts. We have already demonstrated and published in a peer-reviewed pharmacy journal how specially-trained technicians can very accurately stock and check unit-dose medication carts while still incorporating a quality assurance system. It is the use of pharmacy technicians in this capacity that creates the time for pharmacists to utilize their clinical skills to assist physicians and nurses to reduce medication errors at the prescribing and administration steps.

The study is continuing and the results will be presented to the Board upon completion. Should you need additional information about the progress of the experimental program, do not hesitate to contact me at (562) 933-0289.

Respectfully submitted,

Peter J. Ambrose, Pharm.D.
Professor of Clinical Pharmacy
Vice Chair, Department of Clinical Pharmacy
School of Pharmacy
University of California, San Francisco

Enclosure

c: Frank Saya, Pharm.D.
Rita Shane, Pharm.D.

Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration of Medications in the Hospital Setting

Summary of Results

June 21st 2004 – January 1st 2006

A Collaborative Study Between

UNIVERSITY OF CALIFORNIA, SAN FRANCISCO

SCHOOL OF PHARMACY

and the

Pharmacy Services Department of

CEDARS-SINAI MEDICAL CENTER

Background

- Study to determine the impact of pharmacists on prevention of medication errors during the equivalent time spent on checking medication cassettes
- 2 year study (waiver) allows technicians to check technicians filled medication cassettes
- The number and types of medication errors prevented at the prescribing step (order written by the physician) and at the administration step (medication administered by the nurse) of the medication use process will be reported

Study Objectives

- Determine top 10 drugs involved in potential prescribing and administration errors
- Determine type and frequency of medication ***errors intercepted*** at the prescribing and administration steps
- Compare ***intercepted errors*** with USP MedMARX data on errors
- Evaluate factors contributing to prescribing and medication administration errors
- Evaluate potential harm that could have resulted if error was not intercepted

Medication Related Encounters

June 21st 2004 - January 1st 2006 (80 weeks)

Total Medication Related Encounters: **53,247 (665/week)**

- Potential Errors Intercepted (prevented): **1855**

Medication Prescribing :	1241 (67%)
Medication Administration:	614 (33%)

- Other Medication Related Encounters : **51,392**

Pharmacist dosing per MD request:	47,671
STAT orders:	752
Rounds:	169
Code Blue:	56
Drug Information:	2424
Non-Formulary Requests	233
Order Clarifications	87

Medication Prescribing

Potential Errors Intercepted

June 21st 2004 - January 1st 2006 (80 weeks)

- Potential prescribing errors prevented by the pharmacist: 1241
- Orders requiring clarification: 594 (type of error not specified)
- Types of medication ***errors intercepted which prevented****:

Wrong Dose	43 %	Wrong Frequency/Rate	4.2 %
Allergy Contraindication	19.8 %	Wrong Route	3.2 %
Duplication in therapy	10.2 %	Drug Interaction	3.2 %
Necessary medications not ordered	10 %	Wrong Drug	1.5 %
Medication Contraindicated	4.5 %	Wrong Patient	0.4 %

* In those situations where error type was specified

Examples of Medication Prescribing Errors Prevented (5/23/05 – 1/1/06)

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Cyclosporine 2mg/kg/hr ordered	Pharmacist recommended 2mg/kg/day	*Avoided adverse drug reaction (ADR) from overdose*
Oxycontin 80mg Q 4 hr PRN ordered for patients pain control	Pharmacist recommended change to oxycodone immediate release	*Avoided ADR due to excessive accumulation and sub-optimal treatment*
Physician ordered Tacrolimus 5mg/day for transplant rejection	Pharmacist recommended 0.5mg/day	*Avoided potential renal and cardiac toxicity*
Metformin ordered in patient with SCr >2.0	Pharmacist recommended holding Metformin	*Avoided possible ADR including lactic acidosis*
Lovenox ordered for a patient with a SCr < 30ml/min	Pharmacist recommended discontinuation of Lovenox; patient on Coumadin and INR within goal range 2-3	*Avoided increased risk of bleeding*

Examples of Medication Prescribing Errors Prevented (6/21/04 – 5/22/05)

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Ganciclovir: 5mg/kg iv q12h pt s/p kidney transplant & renal insufficiency	Pharmacist recommended 2.5mg/kg/day for CMV induction	*Avoided adverse drug reaction (ADR) from overdose*
Oxaliplatin (chemotherapy) dosage in patient with renal insufficiency	Pharmacist recommended dosage adjustment	*Avoided ADR due to excessive dose of chemotherapy*
Celebrex ordered in patient with sulfa allergy	Pharmacist recommended alternative	*Avoided morbidity associated with an allergic reaction*
Ceftazidime ordered as 1 gm q8h for meningitis in young patient	Pharmacist recommended 2 gm q8h to achieve adequate effect	*Avoided sub-optimal treatment, possible mortality/morbidity*
Lovenox 40 mg daily ordered in patient with chronic renal failure	Pharmacist recommended change to Heparin	*Avoided increased risk of bleeding in patient already receiving blood transfusions*

Medication Administration

Potential Errors Intercepted

June 21st 2004 - January 1st 2006 (80 weeks)

Potential medication administration errors prevented by a pharmacist: 614 encounters

Types of medication ***errors intercepted which prevented:***

Omission of Dose	42.3 %	Wrong Drug	5.1 %
Transcription Error	16.7 %	Drug to be given to patient was not ordered	4.4 %
Wrong Patient	8.2 %	Wrong Route	2.3 %
Extra Dose	7.5 %	Drug Contraindicated	0.2%
Wrong Dose	7.2 %	Drug-interaction	0.2%
Wrong Rate	6.0 %		

Examples of Medication Administration Errors Prevented (5/23/05 – 1/1/06)

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Heparin drip ordered to start at 5AM	Pharmacist identified that heparin was not started	*Avoided delay of therapy and worsening of condition*
Pt was about to receive Vancomycin 750mg q12 hr; order was for 1gm q24h	Pharmacist notified nurse that dose was 1gm and to be given every 24 hr	*Avoided potential renal (kidney) toxicity*
Dilaudid PCA concentration transcribed incorrectly 10mg/ml instead of 1mg/ml	Pharmacist notified nurse	*Avoided sub-optimal treatment*
Chemotherapy dose not administered by nurse	Pharmacist notified nurse about missed chemo dose	*Avoided omission of chemotherapy and worsening of condition*
Nurse requested Depakote 5gm to give to patient	Pharmacist notified nurse about incorrect dose; order was for 500mg	*Avoided potential ADR including cardiac toxicity*

Examples of Medication Administration Errors Prevented (6/21/04 – 5/22/05)

Problem Identified	Pharmacist Recommendation	Outcome Avoided
Pt. scheduled for chemotherapy in AM.	Pharmacist identified that chemo was not given	*Avoided omission of chemotherapy*
Pt was about to receive Tobramycin at a 12 hr interval; order was for q24h	Pharmacist notified nurse that dose was to be given every 24 hr	*Avoided potential renal (kidney) toxicity*
PCA pump was programmed incorrectly	Pharmacist notified nurse	*Avoided potential adverse events associated with excessive narcotic dose*
Pt receiving Potassium Chloride 60meq infusion; order was for 20meq	Pharmacist notified nurse to change infusion	*Avoided potential hyperkalemia and cardiac arrest*
Nurse transcribed Kayexalate when Kaopectate ordered	Pharmacist notified nurse about transcription error	*Avoided potential hypokalemia and cardiac toxicity*

Results compared to USP MedMARX Data

Leading types of errors include:

	USP MedMarx Data 2003[1]	Research Study
Omission error	24 %	20.6 %
Improper dose/quantity	23 %	25.6 %
Unauthorized drug	10 %	2.1 %
Extra dose	5 %	3.7 %
Wrong patient	5 %	4.1 %
Wrong route	2 %	2.8 %

1. http://www.magnetmail.net/actions/email_web_version.cfm?recipient_id=9223078&message_id=63691&user_id=USP

TOP 10 Medications/Classes

June 21st 2004 - January 1st 2006 (80 weeks)

Top 10 medications/classes involved in potential prescribing and administration errors

Medication Prescribing

- Chemotherapy
- Electrolytes
- Enoxaparin (Lovenox)
- Vancomycin
- Warfarin
- Levofloxacin
- Neupogen
- Fluconazole
- Zosyn
- Cefepime

Medication Administration

- Vancomycin
- Heparin
- Chemotherapy
- Electrolytes
- TPN
- Erythropoietin
- Warfarin
- Fluconazole
- Insulin
- Levofloxacin

Preliminary Evaluation of Potential Patient Outcomes

Pharmacist prevented medications errors associated with potential harm: 682

No Harm	339
Temporary Harm	590
Permanent Harm	28
Increase in Length of Stay	60
Death	4

Type of harm unspecified: 834

Factors Contributing to Prescribing Errors

- Incomplete patient information
- Drug allergies overlooked
- Wrong drug name, dosage form or abbreviation
- Incorrect dosage calculations
- Incorrect dosage frequency
- Laboratory results not checked prior to ordering medications
- Concomitant therapy (e.g. supportive drugs for chemotherapy) necessary to prevent adverse reactions not ordered

Factors Contributing to Administration Errors

- Two patient identifiers not used
- Illegible orders
- Drug name confusion
- Incorrect pump programming
- Patients transferred and orders not transcribed accurately
- Environmental factors- distractions, interruptions and significant workload
- Staffing issues- such as shift changes and floating staff

Summary of Study Results to Date

Results of the 80 week study demonstrates the impact of pharmacists on prescribing and administration errors:

- 1855 errors intercepted by the pharmacist
- 51,072 medication related encounters including dosing of medications per MD request, participation in codes, rounds and drug information questions
- Preliminary evaluation of outcomes: 682 pharmacist encounters prevented potential harm of which:
  - 590 prevented temporary harm
  - 28 prevented permanent harm
  - 60 prevented an increase in length of stay
  - 4 prevented death

ATTACHMENT G

California State Board of Pharmacy
1625 N. Market Blvd, Suite N 219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

LICENSING COMMITTEE
Meeting Summary

DATE:	March 22, 2006
TIME:	9:30 a.m. – 12 noon
LOCATION:	Hilton Oakland Airport One Hegenberger Road Oakland, CA 94621
BOARD MEMBERS	Ruth Conroy, Pharm.D., Chair Clarence Hiura, Pharm.D. John Jones, RPh, JD Richard Benson, Public Member
STAFF PRESENT:	Patricia Harris, Executive Officer Virginia Herold, Assistant Executive Officer Robert Ratcliff, Supervising Inspector Dennis Ming, Supervising Inspector

Call to Order

Committee Chair Ruth Conroy called the meeting to order at 9:30 a.m.

Request to Amend 16 CCR § 1728

Pharmacy students from USC and other pharmacy schools presented a proposal requesting that the Board of Pharmacy amend its regulations to allow up to 400 hours that an intern can earn for pharmacy-related experience (under the supervision of a pharmacist) outside a pharmacy. Under current law, an intern must earn a minimum of 900 hours of pharmacy experience under the supervision of a pharmacist in a pharmacy. The board has the discretion to grant a maximum of 600 hours for other experience substantially related to the practice of pharmacy. California pharmacy students earn the 600 hours for school required experiential training (clinical clerkship).

Therefore as proposed, an intern would only need to earn a minimum of 500 hours in a pharmacy and could earn a maximum of 1,000 hours of experience substantially related to the practice of pharmacy under the supervision of a pharmacist.

It was noted that opportunities for pharmacists has expanded beyond the traditional areas of community and hospital practice settings. Many students would like the opportunity to gain experience in the pharmaceutical industry, managed care, regulatory affairs and association management, but are unable to do so because they cannot earn intern hours. As part of the pharmacy school curriculum, students complete various rotations in their first and fourth year in both community and hospital pharmacy. In the fourth year, pharmacy experience is more clinical. It was anticipated that a large percentage of pharmacy students would still earn the majority of the intern hours in a pharmacy. This option would be for those students that show proficiencies in the pharmacy settings and would like to expand their experience in other areas.

The National Oncology Alliance, Inc. (NOA) spoke in support of the proposal and gave a presentation on opportunities that it has for interns outside a licensed pharmacy and under the supervision of a pharmacist. The intern would assist the NOA clinical team to prepare clinical summaries of articles in the medical literature, collect data about the status of drug approvals as it applies to NOA treatment guidelines and assist with the development and yearly revision of NOA treatment guidelines. NOA advocated that patient care activities meet the Accreditation Council for Pharmacy Education (ACPE) criteria and content outline of the California Pharmacy Jurisprudence Examination (CPJE).

The responsibility of the board is to protect the public. It is important that an intern pharmacist is capable of performing the core competencies of pharmacy practice. An intern has the authority to perform all the duties of a pharmacist under the supervision of a pharmacist. There was concern that a minimum of 500 hours of intern experience in a pharmacy is not sufficient to assure adequate public safety and the experience necessary to perform the duties of a pharmacist. It was not clear how experience with a pharmaceutical manufacturer, in regulatory affairs or association management would provide an intern with the skills critical to the practice of pharmacy. The core functions of pharmacy include patient consultation and quality assurance, key skill areas and knowledge that an intern can only gain in real life experience and daily practice in a pharmacy.

The proposal will be placed on the agenda for the April board meeting without a recommendation from the Licensing Committee.

Request from the Accreditation Commission for Health Care, Inc. (ACHC) and the Community Health Accreditation Program (CHAP) to Continue as Board Approved Accreditation Agencies for Pharmacies that Compound Injectable Sterile Drug Products

B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of

Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. At that time, ACHC accredited both home infusion pharmacies and specialty pharmacies that deliver biotech drugs and other specialty products. Recently ACHC has been reviewed by the Center for Medicare and Medicaid Services (CMS) and granted Deeming Authority for Home Health Medicare.

In July 2003, the board approved Community Health Care Accreditation Program (CHAP) as an accreditation agency. CHAPS is a national non-profit accreditation organization established in 1965 to accredit community-based health care organizations. Currently, one California is CHAP accredited and two pharmacies have applied. There are 63 CHAP accredited pharmacies in 23 states and 16 pharmacies that have applied for accreditation.

Supervising Inspector Dennis Ming reported that the board has not found any compliance issues with either ACHC or CHAP accredited pharmacies

In 2003, the Licensing Committee developed criteria for the evaluation of applications by accrediting entities for board approval. It was decided that the evaluation of accrediting agencies for board approval under Business and Professions Code section 4127.1 should be based on the accrediting agency's ability to evaluate the pharmacy's conformance with California law and good professional practice standards and the following factors.

1. **Periodic inspection** – The accrediting entity must subject the pharmacy to site inspection and re-accreditation at least every three years.
2. **Documented accreditation standards** – The standards for granting accreditation and scoring guidelines for those standards must reflect both applicable California law and sound professional practice as established by nationally recognized professional or standard setting organizations.
3. **Evaluation of surveyor's qualifications** – The surveyors employed to perform site inspections must have demonstrated qualifications to evaluate the professional practices subject to accreditation.
4. **Acceptance by major California payors** – Recognition of the accrediting agency by major California payors (e.g., HMOs, PPOs, PBGH, CalPERS).
5. **Unannounced inspection of California accredited sites** – The board must conduct unannounced inspections of two or more accredited sites and find those sites in satisfactory compliance with California law and good professional practice.
6. **Board access to accreditor's report on individual pharmacies.**
7. **Length of time the accrediting agency has been operating.**
8. **Ability to accredit out-of-state pharmacies.** Non-resident pharmacies are eligible for licensure under the sterile compounding statutes and accreditation should be equally available to both resident and non-resident pharmacies.

The Licensing Committee recommended that the Board of Pharmacy approve ACHC and CHAP for another 3 years as accreditation agencies pursuant to B & P § 4127.1(d) for pharmacies that compound sterile injectable drug products.

Proposal to Add a Regulation to Recognize Approved Accreditation Agencies for Pharmacies that Compound Sterile Injectable Drug Products

B & P § 4127.1 requires pharmacies compounding sterile injectable drug products to obtain a license from the board. In order to obtain such a license the pharmacy must first be inspected by the board and found in compliance with board standards for sterile compounding. The law exempts pharmacies that are accredited by the Joint Commission on the Accreditation of Healthcare Organizations or other accrediting agencies approved by the board from the license requirement as specified in Section 4127.1 (d). Exempted pharmacies must still comply with board regulations regarding sterile injectable compounding, but do not have to obtain a separate license.

The board approved Accreditation Commission for Health Care (ACHC) as an accrediting entity in April 2003. The board granted this approval for 3 years. In July 2003, the board also approved Community Health Care Accreditation Program (CHAP) as an accreditation agency.

Since both agencies have requested that the Board of Pharmacy approve them again as accreditation agencies, and if the approval is granted, it is being recommended that the board pursue a regulation to recognize these agencies in regulation as the Joint Commission on the Accreditation of Healthcare Organizations is recognized in statute.

In addition, it was suggested to include the evaluation factors as part of the regulation, require that the accreditation agency use the board's self-assessment form for sterile injectable compounding pharmacies as part of the survey process, submit a copy of the survey report to the board and the process by which a board may no longer recognize an accreditation agency. If the board agrees with this recommendation, proposed language will be drafted.

The Licensing Committee recommended that the Board of Pharmacy pursue a regulation to recognize ACHC and CHAP as accreditation agencies for sterile injectable compounding pharmacies and specify the requirements and application process for accreditation agencies seeking approval.

Request to Extend the Waiver for the Study of UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Association with Prescribing and Administration in the Hospital Setting"

Peter Ambrose, Professor of Clinical Pharmacy at UCSF and Rita Shane, Director of Pharmacy Services for Cedars-Sinai Medical Center requested an extension of the waiver for the study by UCSF School of Pharmacy and Cedars-Sinai Medical Center entitled, "Evaluation of the Impact of Pharmacists in the Prevention of Medication Errors Associated with Prescribing and Administration in the Hospital Setting." In April 2004, the Board of Pharmacy granted a two-

year waiver for this study. After board approval, the study was subsequently reviewed and approved by the Institutional Review Board at Cedars-Sinai Center and the Committee on Human Research at UCSF. In order to complete the data collection, analysis and review the results, an extension until December 31, 2006 was requested.

This study was a sequel to the successful experimental program that evaluated pharmacy technicians checking another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy.

The purpose of the sequel study is to evaluate the impact of pharmacists in prevention of medication errors associated with prescribing and administering of medications as a result of pharmacists being re-deployed from unit-dose medication cassette checking to more clinical and professional functions. Such functions require special expertise of pharmacists in the management of drug therapy, from which patients will benefit.

Preliminary data from the study was provided to the board at its July meeting. At its last meeting, the board approved a regulation change to allow a specialized trained pharmacy technician to check another pharmacy technician in a unit-dose drug distribution system in a hospital pharmacy that has a clinical program. The proposed regulation change is scheduled for the April board meeting. If the board approves the proposed regulation, it will take approximately 6-9 months before the regulation would become effective.

The Licensing Committee recommended that the Board of Pharmacy extend the waiver until December 31, 2006.

NABP Announcement Regarding the Evaluation Process for Foreign Pharmacy Graduates

The National Association of Boards of Pharmacy (NABP) announced its partnership with the Educational Credential Evaluators, Inc. (ECE) for the educational credential evaluation of applicants to the Foreign Pharmacy Graduate Examination Committee (FPGEC) Certification Program. This partnership will change the method by which foreign pharmacy graduates will be evaluated.

ECE will be responsible for verifying the educational background of the applicant and NABP will verify the applicant's professional licensing and registration information. The foreign graduate will submit all documents directly to ECE for evaluation.

This new partnership is intended to address the increase of workload that this program has experienced over the last few years and improve the processing time for these applicants.

California requires all foreign graduates to be FPGEC certified before they can apply to be licensed as an intern or pharmacist.

Changes to the Pharmacy School Accreditation Procedures by the Accreditation Council for Pharmacy Education (ACPE)

ACPE recently announced changes to its accreditation procedures. After June 30, 2006, ACPE will require that any new doctor of pharmacy program seeking preaccreditation status must progress through both stages of preaccreditation, which is precandidate and candidate phases, before consideration of full accreditation. Prior to this policy change, it was not essential that a program be granted precandidate status before students were admitted.

After June 23, 2006, a new program must achieve precandidate status before admitting students. Should a new program admit students without achieving precandidate status, this will preclude ACPE from considering the program's application for candidate preaccreditation status, and full accreditation cannot be considered until graduation of the first class. Students graduating from a program without candidate status will thus have graduated from a program with no accreditation status and will likely not be eligible for licensure.

This change in policy is consistent with the board's recent regulation change that states that the board will recognize a school of pharmacy that is accredited or granted candidate status by ACPE or schools recognized by the board. The board has recently "recognized" new schools of pharmacy that have been granted precandidate status so that the students can be registered as interns.

Report on ACPE Site Visits

It was reported that board members have been actively participating on the ACPE evaluation teams for the California schools of pharmacy. President Goldenberg participated in the recent evaluation of Western University of Health Sciences College of Pharmacy. Former board member Darlene Fujimoto was on the team that evaluated UC San Diego Skaggs School of Pharmacy. The evaluation conflicted with the board's February meeting so Dr. Fujimoto graciously agreed to be the board's representative. Board member Ruth Conroy will be on the site team for Loma Linda University School of Pharmacy scheduled for April 18th – 20th. ACPE is scheduled to evaluate the Touro University California College of Pharmacy for candidate status on April 25-27, 2006, which conflicts with the board's April meeting. If the ACPE visit cannot be rescheduled then a former board member will serve as a representative on the site team.

Competency Committee Report

Virginia Herold reported that at the October 2005 board meeting, the board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) given on or after April 1, 2006. The board posted the new content outline on the board's Web site and was included in the board's January 2006 newsletter.

The California Pharmacy Jurisprudence Examination (CPJE) handbook is in the process of being updated and will include the new content outline. There is also a sample CPJE exam that is posted on the board's Web site.

The Office of Examination Resources (OER) within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based testing. OER conducted the bidders' sessions on March 3 & 6, 2006. Final bids are due to OER on April 4, 2006. The cost opening is scheduled for April 13, 2006, with a Notice of Intent to Award the Contract on April 21, 2006. The anticipated contract award date is May 8, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

The next CPJE statistical report will cover performance data for 10/1/05-3/31/06. This report should be available at the April board meeting.

Adjournment

Chair Ruth Conroy adjourned the meeting at 12 noon.

ATTACHMENT H

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
APPLICATIONS													
Received													
Pharmacist (exam applications)	79	153	117	75	168	69	63	51					775
Pharmacist (initial licensing applications)	32	439	149	13	215	75	94	16					1033
Intern pharmacist	35	234	232	255	308	53	68	57					1242
Pharmacy technician	369	558	609	556	484	447	450	490					3963
Pharmacy	39	36	30	18	30	30	18	20	32				253
Sterile Compounding	14	10	1	1	3	5	5	3	3				45
Clinics	5	5	1	10	4	2	7	7	2				43
Hospitals	1	2	0	4	4	2	0	0	0				13
Non-Resident Pharmacy	2	7	5	3	5	5	6	3	1				37
Licensed Correctional Facility	0	0	0	0	0	0	0	0	0				0
Hypodermic Needle and Syringes	0	1	0	2	0	0	3	3	0				9
Non-Resident Wholesalers	7	7	5	17	11	15	5	6	12				85
Wholesalers	2	19	2	9	5	2	5	3	4				51
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0				0
Designated Representatives	26	61	51	74	42	56	52	70	58				490
Issued													
Pharmacist	146	334	161	19	224	70	81	21					1056
Intern pharmacist	42	140	272	219	260	81	83	29					1126
Pharmacy technician	438	569	491	443	504	338	485	687					3955
Pharmacy	45	42	31	19	20	20	32	15	44				268
Sterile Compounding	5	5	12	5	4	4	5	5	4				49
Clinics	15	8	7	0	4	5	5	4	12				60
Hospitals	1	5	0	2	4	3	5	1	3				24
Non-Resident Pharmacy	9	3	7	2	3	4	4	3	1				36
Licensed Correctional Facility	0	0	0	0	0	0	0	0	1				1
Hypodermic Needle and Syringes	0	3	0	0	1	2	0	4	0				10
Non-Resident Wholesalers	10	13	5	3	5	2	23	5	4				70
Wholesalers	5	5	5	4	6	0	22	4	3				54
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0				0
Designated Representatives	42	47	33	59	31	31	82	83	88				496

*Denotes updated to include pending files to process and processed pending files.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pending*													
Pharmacist Examination	u/a	u/a	u/a	u/a	u/a	139	u/a	u/a	57				
Intern pharmacist	u/a	u/a	218	u/a	u/a	210	u/a	u/a	222				222
Pharmacy technician	906	668	727	730	964	844	812	863	1015				1015
Pharmacy	43	30	36	42	57	54	46	52	40				40
Sterile Compounding	38	40	33	32	29	32	34	30	29				29
Clinics	48	49	45	53	55	51	48	51	41				41
Hospitals	12	8	7	5	7	12	12	12	9				9
Non-Resident Pharmacy	19	20	14	15	12	11	14	20	20				20
Licensed Correctional Facility	0	0	0	0	0	0	1	1	0				0
Hypodermic Needle and Syringes	1	1	1	4	2	2	0	0	0				0
Non-Resident Wholesalers	54	53	50	49	63	54	55	59	67				67
Wholesalers	24	22	24	24	32	27	31	37	38				38
Veterinary Food-Animal Drug Retailer	0	0	0	0	0	0	0	0	0				0
Designated Representatives	116	130	148	163	174	201	103	124	102				102
Change of Pharmacist-in-Charge													
Received	72	128	128	110	89	99	94	82	153				955
Processed	102	92	97	100	90	149	92	110	0				832
Pending	209	245	276	286	285	197	199	171	324				324
Change of Exemptee-in-Charge													
Received	2	2	0	9	5	4	5	1	4				32
Processed	2	2	0	6	4	11	18	1	4				48
Pending	8	8	8	11	12	13	0	0	0				0
Change of Permits													
Received	33	73	39	69	58	50	36	29	44				431
Processed	21	50	48	69	56	21	31	37	58				391
Pending	171	194	184	184	186	215	220	212	198				198
Discontinuance of Business													
Received	17	17	9	7	8	12	16	18	24				128
Processed	30	1	0	0	0	0	61	0	0				92
Pending	39	55	64	71	79	91	46	64	88				88

*Denotes updated to include pending files to process and processed pending files.

Board of Pharmacy Licensing Statistics - Fiscal Year 2005/06

Renewals Received	JUL	AUG	SEP	OCT	NOV	DEC	JAN	FEB	MAR	APR	MAY	JUN	FYTD
Pharmacist	1019	3078	1398	1362	1136	1245	1334	1181					11753
Pharmacy technician	1279	3553	1500	1503	1348	1380	1620	1494					13677
Pharmacy	591	592	903	493	242	310	407	602					4140
Sterile Compounding	11	44	21	22	7	8	7	15					135
Clinics	60	126	64	79	59	44	80	62					574
Non-Resident Pharmacy	21	26	15	17	9	13	18	24					143
Hypodermic Needle and Syringes	20	35	19	24	39	25	21	23					206
Non-Resident Wholesalers	26	52	23	30	23	7	39	30					230
Wholesalers	25	97	35	33	17	12	56	27					302
Veterinary Food-Animal Drug Retailer	1	3	2	0	1	1	2	0					10
Designated Representatives	111	320	151	132	68	105	236	175					1298

The data for renewals received for March is not yet available.

*Denotes updated to include pending files to process and processed pending files.

ATTACHMENT I

California State Board of Pharmacy
1625 N. Market Blvd, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

STATE AND CONSUMERS AFFAIRS AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
ARNOLD SCHWARZENEGGER, GOVERNOR

To: Board Members

Date: April 17, 2006

From: Board of Pharmacy

Subject: Competency Committee Report

New Content Outline for CPJE and

At the October 2005 board meeting, the board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) given on or after April 1, 2006. The board began using the new content outline effective April 1, 2006.

Revised CPJE Handbook

The revised CPJE Handbook was posted on the Web site on April 14, 2006. The revised handbook has a sample CPJE examination for study use. The sample CPJE was also posted on the Web site separately as well.

Exam Result Delay

Periodically, the Board of Pharmacy performs quality assurance assessments to ensure the appropriateness of the California Pharmacist Jurisprudence Examination (CPJE). The board initiated such a study on April 1, 2006. To assure the thoroughness of this assessment, approximately 400 individuals will be needed for participation. Once enough candidates have taken the CPJE, release of examination scores should resume on a weekly basis, usually within 14 days after a candidate takes the examination. Based on the number of candidates who took the CPJE last year during this same period, the board expects to begin releasing scores by the end of June 2006. The board regrets the delay, and will release the scores as soon as it can after it completes the quality assurance assessment.

Test Administration Contract

The Office of Examination Resources within the Department of Consumer Affairs is renewing its contract with a vendor to provide computer based

testing. The board uses this contract's vendor to administer the CPJE. The current contract expires December 1, 2006.

The request for proposal's advertisement publication date was December 2, 2005. The Department released a 9th addendum for the RPF. The addendum resulted in an altered timeline. Final proposals were due to the Department on April 11, 2006, and the cost opening scheduled for April 20, 2006. The contract award date is scheduled for May 15, 2006, with a contract implementation date of November 16, 2006. The duration of the contract is 3 years with 2 one-year optional extensions.

CPJE Statistics

Attached is the CPJE statistical report for October 1, 2005, through March 31, 2006. The overall pass rate for the CPJE is 80.3%.

Board Data for All CPJE Candidates taking examination 10/1/2005 – 3/31/2006

Overall Pass Rates

CPJE

		Frequency	Percent
Valid	F	121	19.7
	P	494	80.3
	Total	615	100.0

NAPLEX

		Frequency	Percent
Valid	F	49	8.9
	P	499	91.1
	Total	548	100.0

Location of School

CPJE

			JPE		JPE Total	NAPLEX		NAPLEX Total
			Fail	Pass		Fail	Pass	
School	California	Count	9	73	82	1	73	74
		% within JPE PF	7.4%	14.8%	13.3%	2.0%	14.6%	13.5%
	Other US	Count	71	282	353	34	290	324
		% within JPE PF	58.7%	57.1%	57.4%	69.4%	58.1%	59.1%
	Foreign	Count	41	138	179	14	136	150
		% within JPE PF	33.9%	27.9%	29.1%	28.6%	27.3%	27.4%
	Unclassified	Count	0	1	1	0	0	0
		% within JPE PF	.0%	.2%	.2%	.0%	.0%	.0%
Total		Count	121	494	615	49	499	548
		% within JPE PF	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Gender

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
gender	F	Count	87	359	446	39	363	402
		% within JPE pass fail status	71.9%	72.7%	72.5%	79.6%	72.7%	73.4%
	M	Count	34	135	169	10	136	146
		% within JPE pass fail status	28.1%	27.3%	27.5%	20.4%	27.3%	26.6%
Total		Count	121	494	615	49	499	548
		% within JPE pass fail status	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

Degree

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
degree awarded	BS Pharmacy	Count	50	160	210	20	157	177
		% within JPE PF	41.3%	32.4%	34.1%	40.8%	31.5%	32.3%
	Pharm D.	Count	71	333	404	29	341	370
		% within JPE PF	58.7%	67.4%	65.7%	59.2%	68.3%	67.5%
	Other	Count	0	1	1	0	1	1
		% within JPE PF	.0%	.2%	.2%	.0%	.2%	.2%
Total		Count	121	494	615	49	499	548
		% within JPE PF	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

California Schools

			JPE pass fail status		JPE Total	NAPLEX pass fail status		NAPLEX Total
			Fail	Pass		Fail	Pass	
school	UCSF	Count	4	15	19	0	18	18
		% within JPE PF	44.4%	20.5%	23.2%	.0%	24.7%	24.3%
	UOP	Count	4	28	32	1	28	29
		% within JPE PF	44.4%	38.4%	39.0%	100.0%	38.4%	39.2%
	USC	Count	0	18	18	0	15	15
		% within JPE PF	.0%	24.7%	22.0%	.0%	20.5%	20.3%
	Western	Count	1	12	13	0	12	12
		% within JPE PF	11.1%	16.4%	15.9%	.0%	16.4%	16.2%
Total		Count	9	73	82	1	73	74
		% within JPE PF	100.0%	100.0%	100.0%	100.0%	100.0%	100.0%

US Schools of Pharmacy

CPJE ONLY

	JPE pass fail status		Total
	F	P	
Samford	0	1	1
U of AZ	0	2	2
UCSF	4	15	19
U of Pacific	4	28	32
USC	0	18	18
U of CO	0	1	1
U of Conn	0	2	2
Howard DC	1	3	4
U of FL	0	2	2
Mercer	0	2	2
U of GA	1	1	2
Idaho SU	0	2	2
U of IL Chi	1	9	10
Purdue	0	5	5
Drake	1	5	6
U of IA	1	2	3
U of KS	0	5	5
U of KY	0	1	1
NE LA U	1	2	3
Xavier	1	2	3
U of MD	1	5	6
MA Col Pharm	10	46	56
NE-MA	0	6	6
Ferris	2	3	5
U of MI	0	2	2
Wayne SU	0	1	1
U of MN	0	3	3
U of MS	0	1	1
St. Louis Col of PH	1	3	4
UMKC	1	1	2
Creighton	4	14	18
U of NE	1	6	7
U of NM	3	9	12
Western	1	12	13
Midwstern U Chicago	0	1	1
A&M Schwartz	6	10	16
St. Johns	1	5	6
SUNY-Buff	0	1	1
Union U	0	2	2
UNC	1	1	2
ND SU	0	1	1
OH Nrthrn U	1	1	2
OH State U	0	5	5
U of Cinn	0	1	1

U of Toledo	1	0	1
SW OK State	1	1	2
U of OK	0	1	1
OR State U	0	5	5
Duquesne	0	3	3
Phl C of Pharm	2	10	12
Temple	5	12	17
U of Pitt	0	2	2
U of RI	0	2	2
Med U of SC	1	0	1
U of SC	2	2	4
TX SO U	2	1	3
U of Hous	0	1	1
U of TX	1	5	6
U of UT	0	3	3
Med C of VA	1	1	2
U of WA	1	4	5
WA State U	1	3	4
U of WI-Mad	0	1	1
U of WY	0	1	1
Campbell U	0	1	1
Nova Southeastern	0	4	4
Wilkes University	1	0	1
Texas Tech	1	0	1
Bernard J Dunn	0	2	2
Midwestern AZ	1	5	6
Nevada College of Pharmacy	9	21	30
MA School of Pharmacy - Worcester	2	15	17
Hampton Universtiy (VA)	0	1	1
unclassified	0	1	1
Other/FG	41	138	179
Total	121	494	615

Graduating school location by country
CPJE Only

	JPE pass fail status		Total
	F	P	
Argentenia	1	0	1
Bangledesh	0	1	1
Bulgaria	0	1	1
Brazil	0	2	2
Canada	0	3	3
Switzerland	1	1	2
China	0	1	1
E&W Germany	0	1	1
Egypt	0	12	12

France	1	0	1
United Kingdom	0	2	2
Indonesia	0	1	1
Ireland	1	0	1
Israel/West Bank/Gaza Strip	0	2	2
India	16	31	47
Iran	0	4	4
Italy	1	1	2
Jordan	0	3	3
Korea (N&S)	2	4	6
S. Korea	0	5	5
Lebanon	0	3	3
Nigeria/New Guinea	1	5	6
Panama	1	1	2
Philippines	7	27	34
Paracel Is	1	0	1
Pakistan	1	1	2
Poland	1	1	2
Sweden	0	1	1
USSR	1	2	3
Syria	2	1	3
Turkey	0	2	2
Taiwan	1	2	3
USA	80	359	439
Vietnam	0	1	1
South Africa	2	13	15
Total	121	494	615

ATTACHMENT J

Licensing Committee

2005-2006
Third Quarter Report
July 1, 2005 – March 31, 2006

Goal 2: **Ensure the professional qualifications of licensees.**

Outcome: **Qualified licensees.**

Objective 2.1: **Issue licenses within three working days of a completed application by June 30, 2006.**

Measures: **Percentage of licenses issued within 3 working days.**

A new tracking system has been implemented.

Tasks: **1. Review 100 percent of all applications within 7 working days of receipt.**

Note: Foreign graduate applications are not being processed (with a few exceptions) because of the changes outlined in SB 1913. Upon completion of the procedures and revision of the necessary forms, the board will resume this workload.

	Apps. Received:				**Average Days to Process:**			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	349	237*	114**		12.5	5.9	8.3	
Pharmacist (initial licensing)	620	290*	110**		4.1	3.4	3.1	
Pharmacy Intern	501	361*	125**		8	10	30	
Pharmacy Technicians	1536	1487*	940**		8	10	14	
Pharmacies	108	65	70		11	15	15	
Non-Resident Pharmacy	14	12	10		9	18	30	
Wholesaler	23	15	12		16	15	30	
Veterinary Drug Retailer	0	0	0		0	0	0	
Designated Representative	138	174	180		6	5	5	
Out-of-State Distributor	19	36	23		19	15	30	
Clinics	11	14	16		13	14	10	
Hypo Needle & Syringe	1	2	6		1	5	10	
Sterile Compounding	25	4	11		2	5	2	

*Denotes information updated to include December 2005 information.
**Denotes January and February 2006 information available at time of report development.

2. **Process 100 percent of all deficiency documents within 3 working days of receipt.**

Average days to process deficiency:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	1-3	3	14	
Pharmacist (initial licensing)	1-3	1	2	
Pharmacy Intern	7	7	30	
Pharmacy Technicians	10	7	10	
Pharmacies	4	10	5	
Non-Resident Pharmacy	9	10	6	
Wholesaler	4	5	6	
Veterinary Drug Retailer	0	0	0	
Designated Representative	1	1	1	
Out-of-State Distributor	4	5	6	
Clinics	2	12	3	
Hypo Needle & Syringe	1	1	1	

3. **Make a licensing decision within 3 working days after all deficiencies are corrected.**

Average days to issue license:

	Q1	Q2	Q3	Q4
Pharmacist (exam applications)	3-5	1	3	
Pharmacist (initial licensing)	3-5	1	2	
Pharmacy Intern	5	5	5	
Pharmacy Technicians	5	5	5	
Pharmacies	3	2	5	
Non-Resident Pharmacy	5	5	5	
Wholesaler	5	5	5	
Veterinary Drug Retailer	0	0	0	
Designated Representative	2	1	1	
Out-of-State Distributor	5	5	5	
Clinics	6	2	1	
Hypo Needle & Syringe	2	1	1	

4. **Issue professional and occupational licenses to those individuals and firms that meet minimum requirements.**

	Q1	Q2	Q3	Q4
Pharmacist	641	313*	102**	
Pharmacy Intern	454	560*	112**	
Pharmacy Technician	1498	1285*	1172*	
Pharmacies	124	68	101	
Non-Resident Pharmacy	19	9	8	
Wholesaler	15	10	29	
Veterinary Drug Retailer	0	0	0	
Designated Representative	122	121	253	
Out-of-State Distributor	28	10	32	
Clinics	30	9	21	
Hypo Needle & Syringe	3	3	4	
Sterile Compounding	22	13	14	

*Denotes information updated to include December 2005 information.
**Denotes January and February 2006 information available at time of report development.

5. **Withdrawn licenses to applicants not meeting board requirements.**

	Q1	Q2	Q3	Q4
Pharmacy Technician	0	0	6	
Pharmacies	0	0	10	
Non-Resident Pharmacy	6	1	0	
Clinics	0	1	0	
Sterile Compounding	0	0	0	
Designated Representative	23	17	62	
Hypo Needle & Syringe	1	0	2	
Out-of-State Distributor	6	5	2	
Wholesaler	5	2	0	

Objective 2.2: **Implement at least 50 changes to improve licensing decisions by June 30, 2006.**

Measure: **Number of implemented changes.**

Tasks: 1. **Review Pharmacist Intern Program.**

9/04 *Governor signed SB 1913 that contained new intern provisions to become effective 1/05.*

9/04 *Licensing Committee recommended changes to 1728 to implement SB 1913.*

9/04	*Licensing Committee recommended a change to 1719 to register interns who are enrolled in a school of pharmacy that has been granted "candidate status" by ACPE.*
9/04	*Licensing Committee recommended omnibus change to 1726 consistent with SB 1913.*
12/04	*Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*
10/05	*Revisions to 1719, 1720, 1726, 1727, and 1728 became effective. Regulation changes were necessary to implement SB 1915.*
1/06	*Received a request from USC to increase the number of hours an intern can earn for pharmacy related experience outside a pharmacy.*
3/06	*Licensing Committee considered a proposal to increase the number of hours that an intern can earn outside a pharmacy to 400 hours. The committee forwarded the proposal to the board without a recommendation.*
	2. Implement changes to the Pharmacy Technician Program.
1/04	*a. Use PTCB as a qualifying method for registration. – Completed.*
1/04	*b. Change education qualifications from A.A. degree in health science to A.A. degree in Pharmacy Technology. – Completed.*
9/04	*c. Eliminate clerk-typist from pharmacist supervisory ratio. Completed – regulation approved by OAL, change effective 10/3/04.*
9/04	*Enforcement Committee recommended technical changes to the regulatory requirements for pharmacy technicians.*
10/04	*Board approved the recommendation and will sponsor legislation in 2005.*
3/05	*SB 1111 (B&P Committee) was introduced.*
1/06	*Pharmacy technician provisions became effective.*
	3. Administer a pharmacist licensure exam more than twice a year.
3/04	*Completed – CA applications began taking the NAPLEX and CPJE.*
9/05	*849 California applicants have taken the NAPLEX and 799 have taken the CPJE since July 1, 2005.*
10/05	*Released CPJE statistics for 4/1/05 – 9/30/05.*

1/06	*1,114 California applicants have taken the NAPLEX and 1,176 have taken the CPJE since July 1, 2005.*
4/06	*Released CPJE statistics for 10/1/05 – 3/31/06 at the April board meeting.*
4/06	*1,306 California applicants have taken the NAPLEX and 1,420 have taken the CPJE since July 1, 2005.*
	4. Assist applicants in preparing to take the California pharmacist licensure examination by developing (or fostering the development of) educational programs and information on how to prepare for the pharmacist exam and by requesting that outside agencies (schools of pharmacy and private educational organizations) develop exam workshops that prepare applicants for the California Pharmacist Exam.
10/05	*Contacted by instructors for potential new exam review course.*
10/05	*The board approved the use of the new content outline for the California Pharmacist Jurisprudence Examination (CPJE) given on or after April 1, 2006.*
12/05	*The board posted the updated Content Outline on the Web site.*
1/06	*Candidates notified through an updated letter sent when they become eligible to take the CPJE informing of them of the change in content outline and effective date of the change. The board has also notified by letter the candidates that were made eligible prior to January 2006, but have not yet taken their CPJE examination.*
2/06	*Supervising Inspector Dennis Ming and Exam Analyst Debbie Anderson provided law and examination information to 80 Western Pharmacy School students.*
2/06	*Supervising Inspector Robert Ratcliff provided information about pharmacy law to 125 students at USCF.*
3/06	*Board Member Ruth Conroy spoke to 50 Touro University pharmacy students on board legislative issues as preparation for their Legislative Day.*
4/06	*Supervising Inspector Dennis Ming presented law review information to UCSF's 4th year students.*
4/06	*The revised CPJE Handbook was posted on the board's Web site. The revised handbook includes a sample CPJE test. The sample CPJE test was also posted on the Web site separately. An email was sent to the board's subscriber list notifying subscribers of the update.*

5/06	*Exam Analyst Debbie Anderson will provide information about examination application to Loma Linda University.*
	5. Develop statutory language to give the Board of Pharmacy the authority to grant waivers for innovative, technological and other practices to enhance the practice of pharmacy and patient care that would have oversight by an independent reviewing body during the study.
	6. Continuously review and develop written exams to ensure they fairly and effectively test the knowledge, skills and abilities of importance to the practice of pharmacy in California.
8/04	*Competency Committee met for two days and developed questions as well as the job analysis.*
9/04	*Competency Committee met for two days and developed questions.*
9/04	*Reported that board will recruit for new competency committee members in its next newsletter (scheduled for November).*
10/04	*Competency Committee met for two days and developed questions.*
11/04	*Job analysis will be released.*
12/04	*Job analysis released to 3,000 pharmacists.*
1/05	*Competency Committee met for two days and developed questions.*
2/05	*Competency Committee met for two days and developed questions.*
4/05	*Competency Committee met for two days and developed questions.*
8/05	*Competency Committee met for two days and developed questions as well as developed the updated Content Outline as a result of the job analysis.*
9/05	*Competency Committee met for two days and developed questions and reviewed the final draft of the Content Outline developed at the August Retreat. Committee forwarded Content Outline to the board for approval.*
10/05	*Competency Committee met for two days and developed questions.*
10/05	*Board approved new Content Outline for use beginning April 1, 2006.*
12/05	*New Content Outline placed on the Web site.*
1/06	*Competency Committee met for two days and developed questions.*
3/06	*Competency Committee met for two days and developed questions.*
4/06	*Competency Committee met for two days and developed questions.*

7. Implement the sterile compounding pharmacy licensing requirements by July 1, 2003.

6/04	*Completed*
9/04	*OAL approved the sterile compounding regulations and will become effective 10/29/04. The clean room requirements will take effect 7/1/05.*
9/04	*Reported that 13 sterile compounding licensed have been issued since July 1, 2004.*
1/05	*Reported that 29 sterile compounding licenses have been issued since July 1, 2004.*
6/05	*Reported that 56 sterile compounding licenses have been issued since July 1, 2004.*
9/05	*Reported that 24 sterile compounding licenses have been issued since July 1, 2005.*
1/06	*Reported that 35 sterile compounding licenses have been issued since July 1, 2005.*
3/06	*ACHC and CHAP submitted requests for re-approval as accreditation agencies for pharmacies that compound sterile injectable drug products. Committee recommended board approval.*
3/06	*Committee proposed a new regulation to define the application process and criteria for approvals of an accreditation agency.*
4/06	*Reported that 47 sterile compounding licenses have been issued since July 1, 2005.*

8. Issue temporary permits whenever change of ownership occurs.

9/05	*1st Quarter – 28 temporary permits issued.*
1/06	*2nd Quarter – 13 temporary permits issued.*
4/06	*3rd Quarter – 34 temporary permits issued.*

9. Establish means for licensee to renew permits on line.

8/04	*Submitted Applicant Tracking System (ATS) report to the department.*
11/04	*Met with the department to discuss conversion to ATS and department prioritization.*
8/05	*Executive Officer participating as sponsor of iLicensing.*

8/05	*Staff begin working with programmers to define business processes for ATS system. Participate in bi-weekly meetings with programmer detailing business requirements.*
9/05	*Staff continue bi-weekly meetings with programmer detailing business requirements.*
9/05	*Staff attend demonstrations for iLicensing software and programs to allow for on-line renewal and applications.*
10/05	*Staff complete definition of business process and cashiering procedures with programmer for ATS* .
10/05	*Staff attend demonstrations for iLicensing software and programs to allow for on-line renewal and applications.*
11/05	*iLicensing FSR submitted to Department of Finance.*
12/05	*iLicensing FSR approved.*
3/06	*Spring Finance letter approved – project to begin 7/06.*
	10. Implement Changes to Facilities Licensure Requirements
9/04	*Governor signed SB 1913 that included application requirements for all applicants.*
9/04	*Governor signed SB 1307 and AB 2682 to clarify the licensure of wholesale and non-resident wholesale facilities.*
9/04	*Staff with legal counsel reviewed application process for wholesalers and non-resident wholesalers.*
1/05	*New application forms are available for nonresident wholesalers.*
1/05	*New application forms are available for wholesalers.*
2/05	*Initiate review of clinic application requirements.*
3/05	*Initiate review of community pharmacy application requirements.*
3/05	*Initiate implementation of the surety bond requirement.*
6/05	*Submitted proposed change to clinic application requirement.*
8/05	*Staff complete draft forms to implement surety bond requirements for wholesalers and out of state distributors.*

9/05	*Staff begin working with consultant to modify existing system to accommodate changes in wholesaler and out of state distributor requirements.*
9/05	*Initiate review of pharmacy application requirements.*
9/05	*Initiate review of licensed sterile compounding application requirements.*
10/05	*Staff revise surety bond form. Form submitted to the Office of the Attorney General for approval.*
10/05	*Article published in The Script detailing surety bond requirements.*
12/05	*Letters sent to wholesalers and out of state distributors notifying them bond requirements.*
12/05	*Programming begins on changes for the surety bond requirement.*
3/06	*Testing begins on programming changes.*
4/06	*Partial implementation of programming changes.*

11. Review the Ownership of Pharmacies

7/04	*Counsel provided guidance on applicants who have prescriber spouses and/or a prescriber who shares a financial interest.*
3/06	*Project to be completed by 12/06.*

12. Review the law regarding candidates who fail the pharmacist licensure exam 4 times or more who are required to take an additional 16 units of pharmacy education.

7/04	*Draft report provided to the board.*
9/04	*Governor signed SB 1913 to extend statutory provision to the board's next Sunset review date (2007).*
9/04	*Licensing Committee recommended omnibus regulation change to update section 1725 regarding acceptable pharmacy coursework for these candidates.*
12/04	*Report provided to the Legislature.*

13. Evaluate application requirements for all licenses.

9/04	*Governor signed SB 1913 that gives the board clear authority to request information needed to evaluate the qualifications of any applicant.*

9/04	*Licensing Committee recommended regulation changes to implement SB 1913 related to application process for the pharmacist licensure exam (1720).*
9/04	*Licensing Committee recommended a legislative change to eliminate the rules of professional conduct required with each application.*
9/04	*Licensing Committee recommended omnibus legislative changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*
9/04	*Licensing Committee recommended changes to 1706.2 to require an eligible applicant to take the licensure exam within 1 year and obtain a license within 1 year of passing the exams.*
9/04	*Licensing Committee recommended a change to 1719 that authorizes an applicant to sit for the pharmacist licensure exam who has graduated from a pharmacy school granted "candidate" status by ACPE.*
10/04	*Board approved statutory proposal to eliminate the rules of professional conducted required for each application and omnibus changes to Business and Professions Code 4053, 4127.5, 4205, 4206 and 4400.*
12/04	*Revised application and instructions to reflect changes from SB 1913 effective 1/1/05.*
3/05	*SB 1111 (B&P) introduced that contains statutory changes to eliminate "Rules of Professional Conduct."*
9/05	*SB 1111 passed.*
10/05	*Regulation changes to 1706.2 and 1719 became effective.*
1/06	*Eliminated Rules of Professional Conduct.*
	14. Review the law regarding the educational requirements of graduates from foreign pharmacy schools.
9/04	*Governor signed SB 1913 that requires a foreign pharmacy school graduate to be certified by the Foreign Pharmacy Graduate Examination Committee.*
9/04	*Licensing Committee recommended that board amend its regulation to eliminate the foreign graduate evaluation application process and fee.*
9/04	*Sent a letter to all pending foreign graduates advising of law change and suspending application process.*
12/04	*Sent letter to all foreign graduate exam applicants not certified about revised exam eligibility status.*

10/05	*Regulation change to 1720.1 became effective. Regulation change necessary to implementation of SB 1913.*
3/06	*Report that NABP/FGPEC will be using a contractor to evaluate transcripts with the goal of improving the process.*

15. Review the law regarding continuing education (CE) requirements for pharmacists.

7/04	*Board approved recommendations from the Pharmacy Foundation of California to update the CE statute and regulation.*
9/04	*Licensing Committee recommended changes to the CE statute to relocate from regulation the 30-hour requirement, to exempt all newly licensed pharmacist from CE requirements for two years and to renew the pharmacists license as "inactive" when a pharmacist fails to certify their CE credits.*
9/04	*Licensing Committee recommended revisions to the CE regulations.*
10/04	*Board approved recommended statutory and regulatory revisions to CE requirements.*
1/05	*SB 1111 (B&P) introduced that contains CE provision.*
6/05	*Reviewed the Pharmacist Self-Assessment Mechanism (PSAM) available from the National Association of Boards of Pharmacy (NABP) and determine options for pharmacists to obtain CE for completing the assessment. Determined what other competency assessments that available.*
9/05	*Licensing Committee recommended 6 hours of CE for completing PSAM.*
10/05	*Revised CE regulations became effective.*
10/05	*Board approved 6 hours of CE for the completion of PSAM.*
1/06	*Implementation of new CE provision regarding renewals of inactive pharmacists' license for failure to verify CE.*
1/06	*Article in newsletter detailing changes in CE requirements.*
2/06	*Request submitted to department to make changes to CAS system to automate process.*
4/06	*Web site updated to reflect regulation changes for petitions of non-recognized providers as well as CE requirements for newly licensed pharmacists.*

16. Review the license of city and county jails and juvenile facilities.

8/04 *Staff met with Board of Corrections to discuss the dispensing process at these facilities and the regulatory structure, which have no effect of law.*

17. Review the certification process for foreign graduates that was implemented 1/05 and the Test of Spoken English (TSE requirement).

3/05 *Licensing Committee discussed the certification process and TSE requirement. Requested TSE presentation at future board meeting.*

18. Implement a temporary permit for a sterile compounding pharmacy.

9/05 *Submitted proposed statutory changes to Licensing Committee. Licensing Committee recommended board approval.*

10/05 *Board approved statutory proposal.*

1/06 *Submitted to B&P Committee as omnibus provision.*

19. Review the license of pharmacies in correctional facilities.

7/05 *Staff met with the Department of Corrections to discuss the distributions and dispensing process at these facilities and the regulatory structure of Pharmacy Law.*

11/05 *Received request from Department of Corrections.*

20. Review the licensure requirements for clinics.

3/05 *Proposal submitted to update the license requirements for clinics.*

6/05 *Licensing Committee recommended approval of statutory changes.*

7/05 *Board approved statutory changes to clinic requirements.*

12/05 *Met with representatives from the UC System regarding the license and distribution requirement.*

1/06 *Submitted to B&P Committee as omnibus provision.*

21. Review the request from University of Touro School of Pharmacy to be board recognized.

9/05 *Licensing Committee recommended approval to recognize University of Touro School of Pharmacy.*

10/05 *Board recognized the University of Touro School of Pharmacy.*

22. Participate in the Accreditation Council for Pharmacy Education (ACPE) evaluation of California schools of pharmacy.

1/05	*Board Member Ruth Conroy participated in the ACPE review of Loma Linda University School of Pharmacy.*
2/05	*Board Member Ken Schell participated in the ACPE review of UC San Diego School of Pharmacy.*
4/05	*Board Member Dave Fong participated in the ACPE pre-candidate review of University of Touro.*
1/06	*Board Member Stan Goldenberg participated in the ACPE review of Western University.*
1/06	*Former Board Member Darlene Fujimoto participated in the ACPE review of UC San Diego.*
	23. Review the license requirements and drug distribution for clinics within the University of California.
12/05	*Met with representatives to discuss current requirements and the UC system drug distribution process.*

Objective 2.3:	**Evaluate five emerging public policy initiatives affecting pharmacists' care or public safety by June 30, 2006.**
Measure:	**Number of public policy initiatives evaluated.**
Tasks;	**1. Explore the need to regulate pharmacy benefit managers.**
10/03	*Board concluded not to regulate PBMs.*
9/04	*Governor vetoed AB 1960 which would have required the regulation of PBMs by the Department of Managed Health Care.*
1/05	*AB 78 introduced to define PMBs and require specified disclosures to purchases.*
9/05	*Governor vetoed AB 78.*
	2. Explore the need to regulate drugs labeled for "veterinary use only."
9/03	*SB 175 was introduced and signed (Chaptered 250, Statutes 2003).*
1/04	*Completed.*
	3. Explore the importation of drugs from foreign countries.
7/04	*Discussed at July Board meeting.*
9/04	*Discussed at September Enforcement Committee meeting.*
9/04	*Governor vetoed SB 1449 which would have required the board to approve Web sites for Canadian pharmacies.*
10/04	*Discussed at October board meeting.*
12/04	*Discussed at December Enforcement Committee meeting.*
12/04	*HHS released its report of the Task Force on Drug Importation.*
1/05	*Discussed at January board meeting.*
3/05	*Discussed at March Enforcement Committee Meeting.*
4/05	*Discussed at April board meeting.*
6/05	*Discussed at June Enforcement Committee Meeting.*
7/05	*Discussed at July board meeting.*
9/05	*Discussed at September Enforcement Committee Meeting.*

10/05	*Discussed at October board meeting.*
12/05	*Discussed at December Enforcement Committee Meeting.*
	4. Develop language and pursue a regulation change to allow the central fill of medication orders for inpatient hospital pharmacies.
9/04	*OAL approved regulation change and will take effect 10/22.*
10/04	*Completed.*
	5. Establish a workgroup with DHS-State Food and Drug on pharmacy compounding
9/04	*Held third meeting of workgroup on compounding – proposed draft concept on general compounding.*
12/04	*Held fourth meeting of workgroup on compounding – recommending statutory proposal.*
12/04	*Licensing Committee recommended approval of statutory proposal to define general compounding and regulatory parameters.*
1/05	*Board approved general compounding proposal.*
2/05	*AB 595 was introduced and sponsored by the board.*
8/05	*AB 595 opposed by DHS – negotiating amendments.*
12/05	*AB 595 still pending.*
3/06	*AB 595 still pending.*
	6. Approve a statewide protocol for emergency contraception (ec) to permit pharmacists to furnish ec pursuant SB 490 (Chapter 651, Statutes of 2003.)
7/04	*Protocol on Web site.*
7/04	*Board approved regulation on protocol.*
9/04	*Regulation submitted to OAL for approval.*
11/04	*OAL approved regulation, which became effective 12/04.*
11/04	*Completed.*

7. Establish a regulatory structure to authorize the dispensing of drugs by veterinarian schools.

9/04 *Governor signed SB 1913 that provides authority.*

8. Consider a waiver pursuant to CCR, Title 16, Section 1706.5 from Cedars-Sinai Medical Center (CSMC) to conduct a study with UCSF, School of Pharmacy to determine the impact of using technician check technicians to fill unit dose cassettes on patient care.

4/04 *Board approved waiver for two years.*

7/05 *CSMC presented preliminary results of the study.*

3/06 *CSMC/UCSF requested extension of waiver until 12/31/06. Licensing Committee recommended board approval.*

9. Development of Proposal for Pharmacist Performing DUR, Medication Therapy Management, Pharmacist Call Centers and Central Processing of Prescriptions for CA patients.

12/04 *Licensing Committee discussed concepts related to proposal.*

3/05 *Licensing Committee discussed draft and proposal.*

6/05 *Licensing Committee discussed draft and proposal.*

9/05 *Licensing Committee discussed draft and proposal.*

12/05 *Licensing Committee recommended statutory amendments to update the definition of pharmacy practice by a pharmacist, a pharmacy and non-resident pharmacy.*

2/06 *Board approved recommended statute changes.*

3/06 *AB 2408 was introduced.*

Objective 2.4:	**Cashier 100 percent of all application and renewal fees within two working days of receipt by June 30, 2006.**
Measure:	**Percentage of cashiered application and renewal fees within 2 working days.**
Tasks:	**1. Cashier application fees.**
9/05	*1st Quarter - The average processing time for processing new application fees is 2-3 working days.*
1/06	*2nd Quarter - The average processing time for processing new application fees is 2-3 working days.*
4/06	*3rd Quarter - The average processing time for processing new application fees is 2-3 working days.*
	2. Cashier renewal fees.
9/03	*The board lost its renewal cashier in October 2001 and has been unsuccessful in obtaining a freeze waiver to fill this position. The average processing time for processing renewal fees in house is 10 days.*
8/04	*Held interviews for renewal cashier because hiring freeze was lifted.*
10/04	*Filled vacancy for renewal cashier.*
9/05	*1st Quarter - Average processing time for central cashiering is 2-3 weeks.*
10/05	*Staff attended a user group meeting and discussed concern about processing time for central cashiering.*
1/06	*2nd Quarter - Average processing time for central cashiering is 2-3 weeks.*
4/06	*3rd Quarter - Average processing time for central cashiering is 2-3 weeks.*
Objective 2.5:	**Respond to 95 percent of all requests for - of licensing information within 5 working days by June 30, 2006.**
Measure:	**Percentage response for verifying licensing information within 5 working days.**
Tasks:	**1. Respond to requests for licensing verification.**
9/05	*1st Quarter – Processed 157 license verifications.* *(Updated to reflect statistics based on the fees collected)*
1/06	*2nd Quarter – Processed 221 license verifications.* *(Updated to include December 2005.)*

	4/06	*3rd Quarter – Processed 116 license verifications..* *(January and February 2006 information available at time of report.)*
Objective 2.6:		**Update 100 percent of all information changes to licensing records within 5 working days by June 30, 2005.**
Measure:		**Percentage of licensing records changes within 5 working days**
Tasks:		**1. Make address and name changes.**
	9/05	*1st Quarter – Processed 1,241 address changes.*
	1/06	*2nd Quarter – Processed 1,525 address changes.*
	4/06	*3rd Quarter – Processed 1,749 address changes.*
		2. Process discontinuance of businesses forms and related components.
	9/05	*1st Quarter – Processed 31 discontinuance- of-business forms. Processing time is 30 days.*
	1/06	*2nd Quarter – Processed 31 discontinuance- of-business forms. Processing time is 30 days.*
	4/06	*3rd Quarter – Processed 58 discontinuance- of-business forms. Processing time is 40 days.*
		3. Process changes in pharmacist-in-charge and exemptee-in-charge.
	9/05	*1st Quarter – Processed 291 pharmacist-in-charge changes. Average processing time is 14days. Processed 4 exemptee-in-charge changes. The average processing time is 5 days.*
	1/06	*2nd Quarter – Processed 339 pharmacist-in-charge changes. Average processing time is 14 days. Processed 21 exemptee-in-charge changes. The average processing time is 5 days.*
	4/06	*3rd Quarter – Processed 202 pharmacist-in-charge changes. Average processing time is 14 days. Processed 23 exemptee-in-charge changes. The average processing time is 7 days.*
		4. Process off-site storage applications.
	9/05	*Processed 14 off-site storage applications.*
	1/06	*Processed 20 off-site storage initial applications and 5 reissued off-sites storage applications.*

4/06	*Processed 24 off-site storage initial applications and 5 reissued off-sites storage applications.*
	5. Process change-of-permit applications.
9/05	*1st Quarter – Processed 119 applications. Average processing time is 30 days.*
1/06	*2nd Quarter – Processed 146 applications. Average processing time is 30 days.*
4/06	*3rd Quarter – Processed 126 applications. Average processing time is 35 days.*