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NONPRESCRIPTION MEDICATIONS AND SELF-CARE

Nonpresciption Medicines and the North American Pharmacist Licensure Examination

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The North American Pharmacist Licensure Examination (NAPLEX) is currently used by all 50 state boards of pharmacy to aid in determining whether a candidate for licensure possesses the minimal knowledge and skills required to safely and effectively practice pharmacy. The blueprint for this examination periodically undergoes revision so that it remains current with the demands and trends of modern-day pharmacy practice. During the most recent revision, which occurred between 2002 and 2004, several substantial content changes were incorporated. One of the most notable changes was the elimination of any distinction of importance between prescription and nonprescription medications. This change was in response to several factors, including the growing variety of conditions for which nonprescription medications are available and the recent switching of several pharmaceutical products from prescription-only to nonprescription status. The previous example is indicative of how the practice of pharmacy is continually evolving and the need for periodic changes to the examination used in the licensure process. As such, the NAPLEX blueprint is continually reviewed and revised to ensure it includes the most current knowledge and skills required of entry-level practitioners.

Keywords: examination, licensure, National Association of Boards of Pharmacy (NABP), nonprescription medicines, prescription medicines, North American Pharmacist Licensure Examination (NAPLEX)

INTRODUCTION

The primary purpose of the North American Pharmacist Licensure Examination (NAPLEX) is to assist the state boards of pharmacy with their responsibility to license as pharmacists only those individuals who are uniquely qualified. This examination serves as an evaluation tool for assessing a candidate's ability to practice entry-level pharmacy in a safe and effective manner. Periodically, the NAPLEX blueprint, the content outline which defines the various types of questions included in each examination, is reviewed and revised to reflect the most current knowledge and skills required for pharmacy practice at an entry level. In conjunction with the most recent blueprint analysis, the NAPLEX Review Committee (NRC), a panel of experts who aid the National Association of Boards of Pharmacy (NABP) in developing and maintaining the NAPLEX, determined that it was no longer valid to assess nonprescription and prescription medication knowledge differently in regard to question development and examination administration. Consequently, there are a greater number of competencies within the NAPLEX blueprint on which questions may be asked regarding nonprescription medications, dietary supplements, and self-care.

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Background Information About NAPLEX

The NAPLEX is a computer-adaptive examination used to determine a candidate's ability to practice entry-level pharmacy safely and effectively. Passing the NAPLEX is part of the licensure process in all 50 states and 3 United States territories (ie, Puerto Rico, the District of Columbia, the Virgin Islands).

The computer-based format of the NAPLEX was first employed in March 1997 and evolved from the traditional paper-and-pencil National Association of Boards of Pharmacy Licensing Examination (NABPLEX) which was administered from 1979 to early 1997. The NABPLEX was based on a 5-part integrated blueprint derived from the original 5-part (ie, pharmaceutical mathematics, pharmacology, pharmaceutics, medicinal chemistry, and pharmacy practice) Blue Ribbon licensing examination that preceded it. To ensure the modern NAPLEX blueprint would be up-to-date with current practice standards, a formal practice analysis was conducted to identify the roles

and responsibilities of entry-level practitioners. The results of this analysis led to the assembly of the 3-part NAPLEX blueprint. This blueprint remained unchanged and in effect through April 2005.

In May 2005, a revised NAPLEX blueprint was introduced. The process of updating the NAPLEX blueprint began in 2002 with a critical review of the existing blueprint by the NRC at its annual meeting. Members of the NRC believed that overall, no substantial revisions were necessary, but identified some specific practice activities that could be added to the content outline. The committee spent the next several months reviewing documents pertinent to pharmacy practice, pharmacy education, and the specific knowledge and skills required of an entry-level practitioner. From these documents and discussions among the committee members came suggested changes, including additions to the content outline as well as a reorganization of the existing competency statements. In spring 2003, the revised blueprint was forwarded to and approved by NABP's Advisory Committee on Examinations and Executive Committee.

In June 2003, a survey instrument with questions regarding the revised blueprint was distributed to several thousand practicing pharmacists in the United States. The results of this survey were analyzed and used to determine the final changes and content distribution for the revised blueprint (Appendix 1). Once the revisions were finalized, a new passing-standard study was conducted. This step was required to ensure that the standard for minimally acceptable performance on the examination incorporates any substantial changes made to the blueprint. This in-depth study was completed in mid-2004. A detailed explanation of the revised blueprint and passing standard was communicated to the state licensing boards and colleges and schools of pharmacy in the fall of 2004.

Treatment of Nonprescription Medications Within the NAPLEX Blueprint

The revised NAPLEX blueprint retains much of the structure and form of the previous blueprint. The examination still covers 3 major areas, which are further divided into multiple competency and sub-competency statements (Appendix 1). The allocation of questions among the 3 areas is different with additional content in the first 2 areas and a corresponding decrease in the number of questions in the third area. The most ubiquitous change was incorporating the concept of pharmacist communication with patients and other health care providers into all aspects of the blueprint instead of limiting it to the third area as it was in the previous blueprint.

Several new concepts were incorporated into the revised blueprint as well. There is now a dedicated sub-competency statement related to the uses, adverse effects, and toxicities of dietary supplements. While this particular statement is new, dietary supplements have been part of the NAPLEX examination since 2003. A new sub-competency statement related to pharmacotherapeutic equivalents was also added because pharmacists are increasingly called upon to consider, and when warranted recommend, therapeutic alternatives.

Perhaps one of the most notable changes was the elimination of any distinction of importance between prescription and nonprescription medications. Within the previous classification structure, examination items that pertained to nonprescription medications were classified only under a handful of competency statements. Because this number constituted a smaller percentage of the total number of competency statements, the potential number of questions on nonprescription medications in a typical NAPLEX examination was also relatively small.

As the NRC was revising the NAPLEX blueprint, the Committee determined that differentiating between prescription and nonprescription medications was unnecessary and unfounded. Several factors led to this determination. First, from a therapeutics standpoint there did not appear to be a reason to treat prescription and nonprescription medications differently. A medication is not resigned to nonprescription status because it is less effective or less important. Rather, the prescription vs. nonprescription status is determined by factors such as a patient's ability to self-administer the medication safely and a low potential for misuse or abuse.

Second, the NRC acknowledged that some prescription medications were also available without a prescription when used for a different clinical indication. For example, meclizine, in 25-mg tablets, is a prescription-only drug when used for vertigo, but is available without a prescription when used to treat motion sickness.

Third, many prescription medications are available without a prescription in lower strengths. This list includes medications from classes including nonsteroidal antiinflammatory medications (eg, ibuprofen and naproxen) as well as histamine-blockers (eg, ranitidine and cimetidine). Additionally, the Food and Drug Administration (FDA) had recently approved moving higher strengths of ranitidine and cimetidine from prescription-only to nonprescription status.

Finally, when the FDA approved switching loratadine and omeprazole to nonprescription status, it set a precedent for additional status changes. The NRC anticipates that more medications used to treat chronic conditions will eventually move to nonprescription status. Several other prescription medications, including orlistat, have recently been reviewed by FDA for potential nonprescription

distribution and sales. Subsequently, orlistat has been recommended by the FDA joint advisory panel, ie, Endocrinology and Metabolic Drugs, for nonprescription sales under the trade name of Alli.

As a result of this change in perception of nonprescription drugs, the NRC elected to eliminate almost every distinction between nonprescription and prescription medications within the NAPLEX. Within the classification system established by the new blueprint, any reference to the term "medication" can appropriately refer to either a prescription or nonprescription medication. In effect, this opens up a broader range of topics within the NAPLEX blueprint on which questions may be asked regarding nonprescription medications. The one notable exception is that the Committee continues to believe knowing which medications are available without a prescription is an important concept. Consequently, the current NAPLEX blueprint includes a competency statement which indicates that a candidate must be able to identify which medications are available on a nonprescription basis (Appendix 1; Area 2, subcompetency 2.2.2).

SUMMARY

The NAPLEX is currently a required part of the pharmacist licensure process in all 50 states and 3 US territories. For the examination to remain a valid instrument for assessing a candidate's ability to practice entry-level pharmacy in a safe and effective manner, the blueprint that makes up this examination must remain current with the knowledge and skills required of entry-level pharmacy practice. The NAPLEX blueprint is reviewed on a continual basis and revised periodically based on changes in entry-level pharmacy practice. Several noteworthy changes in the most recent revision include a broader emphasis on pharmacist communication skills, the addition of subcompetency statements regarding dietary supplements and pharmacotherapeutic equivalents, and the elimination of any distinction of importance between prescription and nonprescription medications. As the demands of entry-level pharmacy practice evolve, NABP will continue to review and revise the NAPLEX blueprint to ensure that it fulfills the mission of assessing a candidate's ability to safely and effectively practice pharmacy.

Appendix 1. NAPLEX Competency Statements (effective May 2005 – present)

Area 1 Assure Safe and Effective Pharmacotherapy and Optimize Therapeutic Outcomes (Approximately 54% of Test)

1.1.0 Obtain, interpret and evaluate patient information to determine the presence of a disease or medical condition, assess the need for treatment and/or referral, and identify patient-specific factors that affect health, pharmacotherapy, and/or disease management.

- 1.1.1 Identify and assess patient information including medication, laboratory and disease state histories.
- 1.1.2 Identify and/or use instruments and techniques related to patient assessment and diagnosis.
- 1.1.3 Identify and define the terminology, signs, and symptoms associated with diseases and medical conditions.
- 1.1.4 Identify and evaluate patient factors, genetic factors, biosocial factors, and concurrent drug therapy that are relevant to the maintenance of wellness and the prevention or treatment of a disease or medical condition.

1.2.0 Identify, evaluate, and communicate to the patient or health-care provider, the appropriateness of the patient's specific pharmacotherapeutic agents, dosing regimens, dosage forms, routes of administration, and delivery systems.

- 1.2.1 Identify specific uses and indications for drug products.
- 1.2.2 Identify the known or postulated sites and mechanisms of action of pharmacotherapeutic agents.
- 1.2.3 Evaluate drug therapy for the presence of pharmacotherapeutic duplications and interactions with other drugs, food, diagnostic tests, and monitoring procedures.
- 1.2.4 Identify contraindications, warnings and precautions associated with a drug product's active and inactive ingredients.
- 1.2.5 Identify physicochemical properties of drug substances that affect their solubility, pharmacodynamic and pharmacokinetic properties, pharmacologic actions, and stability.
- 1.2.6 Interpret and apply pharmacodynamic and pharmacokinetic principles to calculate and determine appropriate drug dosing regimens.
- 1.2.7 Interpret and apply biopharmaceutic principles and the pharmaceutical characteristics of drug dosage forms and delivery systems, to assure bioavailability and enhance patient compliance.

1.3.0 Manage the drug regimen by monitoring and assessing the patient and/or patient information, collaborating with other health care professionals, and providing patient education.

- 1.3.1 Identify pharmacotherapeutic outcomes and endpoints.
- 1.3.2 Evaluate patient signs and symptoms, and the results of monitoring tests and procedures to determine the safety and effectiveness of pharmacotherapy.

1.3.3 Identify, describe the mechanism of, and remedy adverse reactions, allergies, side effects and iatrogenic or drug-induced illness.
1.3.4 Prevent, recognize, and remedy medication non-adherence, misuse or abuse.
1.3.5 Recommend pharmacotherapeutic alternatives.

Area 2 Assure Safe and Accurate Preparation and Dispensing of Medications (Approximately 35% of Test)

2.1.0 Perform calculations required to compound, dispense, and administer medication.
2.1.1 Calculate the quantity of medication to be compounded or dispensed; reduce and enlarge formulation quantities and calculate the quantity of ingredients needed to compound the proper amount of the preparation.
2.1.2 Calculate nutritional needs and the caloric content of nutrient sources.
2.1.3 Calculate the rate of drug administration.
2.1.4 Calculate or convert drug concentrations, ratio strengths, and/or extent of ionization.

2.2.0 Select and dispense medications in a manner that promotes safe and effective use.
2.2.1 Identify drug products by their generic, brand, and/or common names.
2.2.2 Determine whether a particular drug dosage strength or dosage form is commercially available, and whether it is available on a nonprescription basis.
2.2.3 Identify commercially available drug products by their characteristic physical attributes.
2.2.4 Interpret and apply pharmacokinetic parameters and quality assurance data to determine equivalence among manufactured drug products, and identify products for which documented evidence of inequivalence exists.
2.2.5 Identify and communicate appropriate information regarding packaging, storage, handling, administration, and disposal of medications.
2.2.6 Identify and describe the use of equipment and apparatus required to administer medications.

2.3.0 Prepare and compound extemporaneous preparations and sterile products.
2.3.1 Identify and describe techniques and procedures related to drug preparation, compounding, and quality assurance.
2.3.2 Identify and use equipment necessary to prepare and extemporaneously compound medications.
2.3.3 Identify the important physicochemical properties of a preparation's active and inactive ingredients; describe the mechanism of, and the characteristic evidence of incompatibility or degradation; and identify methods for achieving stabilization of the preparation.

Area 3 Provide Health Care Information and Promote Public Health (Approximately 11% of Test)

3.1.0 Access, evaluate, and apply information to promote optimal health care.
3.1.1 Identify the typical content and organization of specific sources of drug and health information for both health-care providers and consumers.
3.1.2 Evaluate the suitability, accuracy, and reliability of information from reference sources by explaining and evaluating the adequacy of experimental design and by applying and evaluating statistical tests and parameters.

3.2.0 Educate the public and health-care professionals regarding medical conditions, wellness, dietary supplements, and medical devices.
3.2.1 Provide health care information regarding the prevention and treatment of diseases and medical conditions, including emergency patient care.
3.2.2 Provide health care information regarding nutrition, lifestyle, and other non-drug measures that are effective in promoting health or preventing or minimizing the progression of a disease or medical condition.
3.2.3 Provide information regarding the documented uses, adverse effects and toxicities ofdietary supplements.
3.2.4 Provide information regarding the selection, use and care of medical/surgical appliances and devices, self-care products, and durable medical equipment, as well as products and techniques for self-monitoring of health status and medical conditions.