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December 29, 2004

REPORT TO THE LEGISLATURE REGULAR SESSION 2005, PURSUANT TO ACT 150, SLH 2004

This report is filed pursuant to Act 150, SLH 2004, which requires the Joint Formulary Advisory Committee ("Committee") of the Department of Commerce and Consumer Affairs, to report to the Legislature on its activities and its recommendations with respect to the prescriptive authority formulary for advanced practice registered nurses ("APRN"). The report to the Legislature is also to include a report to the Committee from the Board of Medical Examiners ("BME") that clearly justifies its denial of any recommendations made by the Committee[1].

Report by the Joint Formulary Advisory Committee[2]

The purpose of the Committee is to recommend the applicable formulary for APRNs recognized for prescriptive authority by the BON. The recommended formulary is to be transmitted to the BME who is required to consider the recommendations of the Committee as the BME decides upon and adopts the formulary.

The Committee's foremost purpose is to safeguard the life and health of Hawaii consumers and to this end it first researched the laws relating to APRN prescriptive authority and APRN formularies of the 49 other states. It did a thorough review of the current requirements for APRN prescriptive authority in this State, which includes a master's degree in clinical nursing or nursing science from an accredited school of nursing; current certification in the nursing practice specialty from a recognized national certifying body; successful completion of advanced pharmacology education; a minimum of one thousand hours of clinical experience in an institution as a board-recognized APRN in a nursing practice specialty; and the collegial agreement with two currently licensed physicians. The Committee also considered the safeguards within the DCCA regarding the oversight of the collegial agreement and any changes to the agreement including any changes to the physician/APRN relationship which are immediately shared with all licensed pharmacies in the State.

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[1] In 2004, an annual report was filed pursuant to Act 192, SLH 2002. This 2005 report continues where the 2004 report left off.

[2] The Committee is composed of (1) Two persons licensed as advanced practice registered nurses and appointed by the Board of Nursing ("BON"), resulting in the appointments of Valisa Saunders, MSN, Geriatric Nurse Practitioner and Diane Knight, MSN, Pediatric Nurse Practitioner; (2) Two persons licensed in medicine by the Board of Medical Examiners ("BME"), resulting in the appointments of Glenn Pang, M.D. and John Rausch, M.D.; (3) Three persons licensed as pharmacists and appointed by the Board of Pharmacy ("BOP"), resulting in the appointments of Guy Omura, R.Ph, Steven Scatcherd, R.Ph., and Sean Young, R.Ph.; (4) One representative of the John A. Burns School of Medicine ("JABSOM"), resulting in the appointment of Kelley Withy, M.D.; and (5) One representative from the school of nursing with an APRN program, resulting in the appointment of Anne Leake, Ph.D., APRN.

At the October 10, 2003 BME meeting, Committee members Valisa Saunders, APRN, and Kelley Withy, M.D. were in attendance to answer any questions the BME may have regarding the Committee's August 13, 2003 recommendation[3]. They were apprised that the BME would take the recommendation under advisement. At the following BME meeting held on November 14, 2003, Committee members Ms. Saunders, Dr. Withy and John Rausch, M.D. were in attendance and were informed that the BME did not accept the Committee's recommendation. At this point, the Committee felt that it would not have enough time to work on another recommendation and submit it to the BME for consideration. It then focused on the annual report to the Legislature in accordance with Act 192, SLH 2002.

On June 29, 2004, Act 192 was repealed and Act 150 took effect. Act 150 ensured the continuance of the Committee, required a status report on its activities and recommendations, and added the requirement to have the BME submit a report to the Committee that clearly justifies its denial of any recommendation made by the Committee.

On August 26, 2004, the Committee reconvened and mainly discussed how it could approach the changes to the APRN formulary in a more constructive manner. It decided that through the BME Executive Officer ("EO") who was also in attendance, the BME would be asked to clarify the problems which the BME was concerned with and how the Committee could address these problems. It also extended an invitation to the BME to have its representatives attend future Committee meetings to find out what the BME would consider acceptable in terms of off-label uses and controlled substances.

At its September 9, 2004 meeting, the Committee finalized its third recommendation[4] which the BME EO would convey to the BME at its September 10, 2004 meeting. The BME responded to the Committee's request and decided that Maria Patten, M.D., Cullen Hayashida, public member, and Markus Polivka, public member would represent the BME at the Committee's future meeting. The decision by the Committee and the BME to collaborate on the issues of controlled substances and off-label uses was the turning point of what would become a positive outcome.

BME member Dr. Patten attended the Committee's September 23, 2004 meeting and shared the BME's concern with the Committee's September 9, 2004 proposal. The BME felt that there was a lack of documentation or memorializing of the discussion between the APRN and the physician (with whom the APRN had a collegial agreement) regarding off-label usage. With Dr. Patten's input, the Committee finalized its fourth recommendation[5]. Dr. Patten agreed to share the Committee's recommendation with the BME at its October 8, 2004 meeting. The Committee had the following concerns: (1) Based on the Committee's research, it found that forty-eight other states do not exclude off-label usage by APRNs (data via National Council of State Boards of Nursing and Medscape); (2) That many medications (e.g. albuterol use in asthmatic children less than two years of age) used in basic care are off-label and if withheld by the APRN would constitute malpractice on the part of both the APRN and physician;

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[3] The Committee's second recommendation proposed to add the language, "All medications that are not referenced in current clinical practice guidelines listed by the National Guidelines Clearinghouse ("NGC") or from entities recognized by the NGC; provided an APRN may petition the Board of Medical Examiners for an exemption for specific use of a specific drug for a specific situation." The Committee intended to address both off-label uses and controlled substances, but decided to address one issue at a time. It addressed off-label uses first as it was the most controversial issue in the workplace.

[4] The Committee proposed to amend Item C of the current Exclusionary Formulary by replacing the language with "All off-label or unlabeled uses of medication not discussed with the collegial physician".

[5] The Committee added "(and documented)" to Item C of the current Exclusionary Formulary to read, "All off-label or unlabeled uses of medication not discussed (and documented) with the collegial physician".

(3) If in 1997,the BME's Medical Formulary Committee decided against establishing an inclusionary formulary because a specific listing of drugs was too cumbersome and difficult to keep current, why was the BME again requiring it; and (4) Why would APRNs still be excluded from prescribing controlled substances if the APRNs would be under the supervision of licensed physicians since the guidelines are very similar to that of physician assistants and especially since APRN educational background exceeds that of a physician assistant.

At the October 12, 2004 Committee meeting, BME member Dr. Patten reported that the BME was not in favor of the Committee's fourth recommendation and no written report was provided on the reasons for the rejection. The BME, however, proposed that the Committee have all APRNS with prescriptive authority polled to come up with a common list of drugs which are used off-label as recommended to be included in the Formulary. The BME would then approve the list, then use the list as a reference base and require APRNs to submit any modifications to the list of drugs to the BME subcommittee for approval.

The Committee could not support the development of a common list of drugs which are used off-label because such a list is too cumbersome. The list would also include a list of thousands of drugs which are legally dangerous for the APRN and physician because such a list would become obsolete within nine months. Also, it was concluded in 1997 by the BME Medical Formulary Committee, that it could not timely maintain a list in accordance with the changes in the production of new pharmaceuticals and that there was the legal risk and the risk to client safety in having an incomplete list should the BME fail to timely update it. There were also concerns of resources in terms of personnel to do constant research and to take on the added workload involved in creating and maintaining such a list. Further, as part of its current research of other states laws and formularies, the Committee found that no other state prohibits off-label usage by APRNs, or requires a collegial agreement with a physician, or requires submission of an updated list by each APRN to the BME for approval.

At that point, the Committee referred back to its fourth recommendation, to require APRNs to memorialize the APRN discussion of off-label usage with the collegial physician, to be adequate and more than what the other 48 states require.

After a lengthy discussion, Dr. Patten shared the BME's concerns with outlying settings such as weight loss clinics, hastening death clinics, sleep clinics, and anti-aging clinics, where indiscretion on the part of physicians in allowing off-label usage of medicines could occur, which was of grave concern to the BME, resulting in the counter proposal to develop a list of drugs which are used off-label.

The Committee subsequently prepared an October 15, 2004 memorandum to the BME indicating that the development of a statewide, timely updated list of medicines extracted from every practicing APRN with prescriptive authority in the State is overly burdensome. Instead, the Committee proposed alternatives for consideration. One alternative was the development of an exclusionary list of medical conditions and therapeutic interventions. For example, item C in the Exclusionary Formulary could read: "C. All medications used for (certain disease states or medical /cosmetic purposes) including (listing of medications such as anabolic steroids, phentermine, growth hormone, growth hormone)". Another alternative would be to provide the BME with sample lists of off-label uses of medications from actively practicing APRNs with prescriptive authority to demonstrate what could be requested of APRNs in Hawaii. Dr. Patten agreed to present the Committee's memorandum to the BME.

At the Committee's October 21, 2004, there was no quorum, however, Committee members Drs. Netzer and Patten and the two BME public members discussed the possibility of allowing off-label usage of drugs and allowing APRNs with prescriptive authority to prescribe controlled substances (schedule II to V of Chapter 329, HRS) with a supervisory relationship with a physician. No action could be taken then by the Committee, however, at its November 4, 2004 meeting, the Committee finalized this proposal.

On November 5, 2004 the BME approved proposed changes to the formulary. This collaborative effort by both entities brought about a positive outcome. The amendments to the APRN formulary will provide uniformity with other states' formularies and ensure consumer safety in Hawaii. Attached herein, is the report by the Board of Medical Examiners to the Joint Formulary Advisory Committee, as required by Act 150, SLH 2004, and the new formulary.

A REPORT TO THE

JOINT FORMULARY ADVISORY COMMITTEE

Submitted by the
Board of Medical Examiners
Department of Commerce and Consumer Affairs
State of Hawaii

December 2004

A REPORT TO THE
JOINT FORMULARY ADVISORY COMMITTEE

December 2004

The Board of Medical Examiners ("BME") has revised the Exclusionary Formulary with its philosophy in mind that as a regulatory body, it has the responsibility of protecting the health and safety of the public and maintaining the standards of health care delivery in the community. While access to medical care is a critical public health issue, the primary consideration must always be protection of a public that relies on state regulation to protect it from unqualified practitioners. The BME understands that the way medicine is being practiced nationwide is becoming more interdisciplinary and it is incumbent on the professions involved to work cooperatively to allow for innovation in meeting patient needs in the most effective, efficient and cost-effective manner possible. Decisions to create, change or expand the scope of practice for non-physician practitioners are complex and should be supported by bona fide, anticipated or existing need for the proposed change. Fundamentally, patient safety and public protection must be the primary objectives when evaluating these requests.

All discussion about changes in scope of practice begins with a basic understanding of the definition of the practice of medicine and the recognition that the education received by non-physician practitioners is not equivalent to the education received by a physician. The hours spent in training by a

physician equal many multiples of the hours spent by non-physician practitioners. There are qualitative differences in pre-requisites, content, intensity, learning methods and training of thought processes. Best prescribing practices take into account not only the pharmacology of the medication in question, but the medical, biological, physical, psychological and social factors that are at play with each patient as well as the health interests of the public. The number of hours spent in pharmacology class is only a small part of this equation and is not equivalent to the education of a physician.

Responsibility for the health of the patient and the community is a team effort with ultimate responsibility resting with the physician. The physician has professional and legal responsibility for the performance of the non-physician practitioner under the physician's supervision or with whom the physician is in a professional agreement. Consumers generally trust that non-physician practitioners authorized to provide health care services are qualified, capable, competent and adequately supervised. Appropriate regulation is an important safeguard that ensures public safety and engenders public trust.

The BME first approved the Exclusionary Formulary on January 9, 1998. In 2003, and after a series of meetings, on September 19, 2003 the Joint Formulary Advisory Committee ("Committee") presented their recommendations for amendments to the formulary to the BME. At its October 10, 2003 meeting, the BME had the opportunity to review these revisions and also heard from

Committee members Kelley Withy, M.D., School of Medicine and Valisa Saunders, Board of Nursing ("BON").

The first revision to the formulary related to the off-label or unlabeled uses of medication. Specifically, the Committee proposed that off-label or unlabeled uses be acceptable if the medications are referenced in current clinical practice guidelines listed by the National Guidelines Clearinghouse ("NCG") or from entities recognized by NCG. The second revision related to controlled substances. The Committee proposed that controlled substances be deleted from the formulary and recommended that the BON address this area in its rules. Included in the rules would be the supervision of APRNs by physicians with regard to controlled substances only. The BON and the Committee agreed to the supervision of APRNs by licensed physicians as Keith Kamita, Division Administrator of the Department of Public Safety's Narcotics Enforcement Division, advised that he would not have a problem with APRNs prescribing controlled substances provided that it was done under physician supervision and with the same requirements that are placed on physician assistants. At the conclusion of the October 10, 2003 meeting, the BME took the matter under advisement.

At the November 14, 2003 meeting, the BME again reviewed the Committee's recommendations and heard from Committee members Dr. Kelley Withy, Valisa Saunders and John Rausch, M.D. After discussion, the BME determined that a supervisory relationship should exist with regard to all

medication and not just controlled substances, and that the supervisory relationship should be put in writing. Additionally, the BME would require that there be a ratio of one supervising physician to two APRNs and that the physician and APRN be in the same specialty.

There was also concern with the recommendation regarding off-label or unlabeled uses and in particular, with the NGC practice guidelines.[1] The NGC does not develop and update all the guidelines on its website. Instead, it lists hundreds of guidelines, many on the same condition and some of which disagree with each other.

Therefore, it was believed that the guidelines are not by themselves definitive and cannot stand alone. More acceptable to the BME was a list of specific practice guidelines.

For this reason, the BME believed that clinical judgment was needed to go beyond the Physicians Desk Reference, which is approved by the Federal Drug Administration ("FDA"). As such, the BME felt that use of the guidelines should be linked to approval by the supervising physician. The BME believed that without a supervising physician, the public would be best served by staying with the more conservative FDA-approved indications for the use of drugs.

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[1] At its February 7, 2003 meeting, the BME reviewed a similar revision regarding off-label uses and found it to be acceptable. However, at its March 7, 2003 meeting, it reconsidered the revision and advised the Committee of its concerns. Nevertheless, the Committee believed that specific listing of drugs or drug classifications would be cumbersome and unnecessary. Moreover, it believed that listing specific websites that provide standards of care guidelines could quickly become obsolete and therefore, it preserved the language regarding current standards of care.

Because of these concerns, the BME did not accept the recommendations and asked that the Committee continue its work on the formulary.

Subsequently, on August 26, 2004, the BME's Executive Officer verbally briefed the Committee on the BME's concerns with the recommendations. The Committee determined that it would ask the BME for clarification as to what the BME's specific concerns were and what would be needed to address the concerns. Further, it requested that some BME members attend Committee meetings to help expedite the process.

In response, at the BME's September 10, 2004 meeting, Dr. Netzer, Chair, asked physician member Maria Patten, D.O. and public members Cullen Hayashida and Markus Polivka to serve as the BME's representatives and attend Committee meetings. Further, Dr. Patten was requested to advise the Committee of the Board's concerns. On his part, Chair Dr. Nezter announced that he would do research and gather information, including having discussions with Committee members, in order to get a better sense of the issues. The Chair emphasized that the BME's mission is to protect the public. As there is a high potential for addiction, the BME was concerned about inappropriate prescribing or the misuse of controlled substances. It agreed that patient safety is a priority when making revisions to the formulary.

After attending the September 23, 2004 Committee meeting, BME member Dr. Patten reported back to the BME at the October 8, 2004 meeting.

Discussion continued on the recommendations on controlled substances and off-label or unlabeled uses of drugs. The BME was generally in agreement in allowing APRNs to prescribe controlled substances under certain conditions. With respect to off-label or unlabeled uses, the BME decided to explore establishing a list of all common off-label uses from which an APRN can prescribe.

When BME member Dr. Patten conveyed this to the Committee at its October 12, 2004 meeting, the Committee proposed that the BME establish an excluded list of medical conditions and therapeutic interventions that was of concern to the BME (i.e., weight loss, pain management, etc.).

In response, during the interim between BME meetings, the Chair fashioned a proposal which he shared and discussed with Committee members on October 21, 2004. This draft was agreed to and approved by the Committee on November 4, 2004. The BME subsequently approved the same proposal. Major revisions were made to: 1) off-label or unlabeled uses of medication and 2) controlled substances consisting of the following:

1) Off-label or Unlabeled Uses of Medication:

   The BME was in agreement with the Committee that except for certain conditions, APRNs should be allowed off-label or unlabeled uses of medication within a collegial relationship when prescribing under community based standards of care.

2) Controlled Substances:

The BME's concerns about controlled substances revolved around public health problems posed by the abuse and diversion of these medications as well as the danger potential to patients who overuse them in legitimate circumstances. The BME felt these prescriptions should be written by a limited number of prescribers. This was also the position of Keith Kamita, Division Administrator of the Department of Public Safety's Narcotics Enforcement Division. Therefore, the prescribing of controlled substances was to occur only under certain conditions and within a supervisory relationship with a physician.

The final result is the Exclusionary Formulary attached as Exhibit A.

EXCLUSIONARY FORMULARY

Advanced Practice Registered Nurses (APRN) granted recognition for prescriptive authority (Nurse Practitioner, Clinical Nurse Specialist, and Certified Nurse Midwife) in accordance with Chapters 457, Hawaii Revised Statutes, relating to Nurses and 16-89C, relating to Advanced Practice Registered Nurse Prescriptive Authority, may prescribe drugs that are within the APRNs' scope of practice in a collegial or supervisory working relationship with a physician, as defined in section 16-89C-10, and this Exclusionary Formulary.

Subject to this Exclusionary Formulary, APRNs may prescribe: (1) non-controlled substances when in a collegial working relationship with a physician; and (2) controlled substances when in a supervisory relationship with a physician.

The Exclusionary Formulary shall list drugs or categories of drugs that shall not be prescribed by the APRN recognized to prescribe by the Board of Nursing. Subject to all applicable state and federal laws and rules and this Exclusionary Formulary, the receipt of, the signing for, or the dispensing of professional samples to patients is permissible.

The APRN granted recognition for prescriptive authority accepts responsibility, accountability, and obligation to practice in accordance with usual and customary APRN standards and functions as defined by the scope of practice/role definition statements for the APRN category and specialty.

<u>The Exclusionary Formulary shall consist of:</u>

A. All controlled substances listed in schedule II of Chapter 329, HRS, except:
   i. in hospitals, extended care facilities or hospice settings; and
   ii. within a supervisory relationship with a licensed physician;
B. All controlled substances listed in schedules III through V of Chapter 329, HRS, except within a supervisory relationship with a licensed physician;
C. Notwithstanding A and B above, the Exclusionary Formulary shall also include all:
   i. general anesthetics;
   ii. investigational drugs;
   iii. narcotics and sedatives for treatment of chronic pain and fatigue;
   iv. stimulants and hormones for treatment of obesity; and
   v. human growth hormones, anabolic steroids or hormones for performance enhancement or decreasing the impact of aging.
D. All other drugs or pharmaceuticals which any party of the collegial working relationship excludes in their collegial or supervisory relationship agreement filed with the Department pursuant to section 16-89C-10.

Degree of Supervision

The supervising physician shall:

A. Possess a current unrestricted Hawaii license to practice medicine and surgery that is in good standing with the board;
B. Direct and exercise supervision over the APRN and recognize that the supervising physician retains full professional and legal responsibility for the performance of the APRN and the care and treatment of the patient;
C. Provide adequate means for direct communication between the APRN and the supervising physician; provided that where the physical presence of the supervising physician is not required, the direct communication may occur through the use of technology which may include but is not limited to, two way radio, telephone, fax machine, modem, or other telecommunication device;
D. Personally review the records of each patient seen by the APRN within seven working days;
E. Supervise no more than two APRNs at any one time; and
F. Be authorized to allow the APRN to prescribe and administer medications and medical devices to the extent delegated by the supervising physician and subject to the following requirements:
    i. An APRN who has been delegated the authority to prescribe controlled substances shall register with the Drug Enforcement Administration (DEA); and
    ii. Each prescription written by an APRN shall include the name, address, and phone number of the supervising physician and APRN. An APRN who has been delegated the authority to prescribe shall sign the prescription next to the printed name of the APRN.

Approved by the
Board of Medical Examiners
November 5, 2004