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KENNY C. GUINN
Governor

MICHAEL J. WILLDEN
Director

DEPARTMENT OF HUMAN RESOURCES
DIRECTOR'S OFFICE
505 E. King Street, Room 600
Carson City, Nevada 89701-3708
Telephone (775) 684-4000 • Fax (775) 684-4010
hr.state.nv.us

April 2, 2003

The Honorable Raymond D. Rawson
Chairman, Senate Finance/Ways and Means
Joint Subcommittee on Human Resources
401 S. Carson Street
Carson City, Nevada 89701

Re: S.B. 321 and S.B. 374

Dear Senator Rawson:

This is to inform you of the status of discussions between representatives of the pharmaceutical industry and the Department of Human Resources (DHR) regarding S.B. 321 and S.B. 374. Agreement was reached on many of the issues raised by the State and industry representatives with the exception of implementation of supplemental rebates for prescription drugs on a preferred drug list.

DHR is proceeding to develop a preferred drug list and step therapy protocols in a manner consistent with best clinical practice and in an open and independent forum. DHR will formally adopt regulations to implement these principles and allow full participation by interested parties. The terms of the agreement are outlined as follows:

1. State Maximum Allowable Cost for Generic Drugs - This program will be implemented as defined by the DHCFP in previous public testimony.
2. Preferred Drug List (PDL) – This program will be implemented by the DHCFP in the manner described below:
    a. Drugs to be excluded from the PDL include:
        i. Atypical and typical anti-psychotic medications;
        ii. Anti-HIV/AIDS drugs including protease inhibitors and anti-retroviral medications;
        iii. Anti-seizure medications;
        iv. Anti-rejection medications for transplants;
        v. Anti-diabetic medications;
        vi. Anti-hemophilic medications; and
        vii. Other therapeutic drug classes identified by the Pharmaceutical and Therapeutics (P&T) committee.
    b. P&T Committee:
        i. The committee will be established under the requirements established in §1927 of the Social Security Act. This includes:

1. The membership P&T committee shall include health care professionals who have recognized knowledge and expertise in one or more of the following:
    a. The clinically appropriate prescribing of covered outpatient drugs.
    b. The clinically appropriate dispensing and monitoring of covered outpatient drugs.
    c. Drug use review, evaluation and intervention.
    d. Medical quality assurance.
2. The membership of the committee shall be made up of at least one-third but no more than 51% licensed and actively practicing physicians and one-third licensed and actively practicing pharmacists (or doctors of pharmacy). The members will also be contracted Medicaid providers or work closely with the populations served.

ii. The committee will not exceed 11 members and perhaps be limited to 9 members in order to reduce administrative cost and complexity.

iii. Members would be selected by the Director of the Department based on recommendations. The Director may solicit recommendations for members through public request as well.

iv. The P&T committee will be made up of Nevada-based providers and may seek appropriate consultation from clinical specialists in the areas of pharmacy under review. This may include Nevada-based as well as national clinical thought leaders for the therapeutic class under review.

v. The P&T committee will base its decisions on determination of clinical equivalence of drugs in a therapeutic class based on evidence of clinical efficacy and safety.

vi. The P&T committee will be the final authority in determining whether a therapeutic class of drugs will be considered as part of a preferred drug list as well as the selection of therapeutically equivalent drugs for review by the State.

c. The PDL administrator (contracted vendor) will provide administrative support to the P&T committee.

d. New pharmaceutical products and new evidence of clinical efficacy:

    i. The P&T will review new pharmaceutical products for the PDL in as expeditious a manner as possible.

    ii. The P&T committee will reconsider new clinical evidence supporting the inclusion of a current product as a preferred drug in as expeditious a manner as possible.

    iii. Until a review of a new product or new evidence can be reviewed and decided upon, the State will make the product available with a prior authorization.

e. The P&T committee will review all therapeutic classes on the PDL annually.

f. Continuity of care decisions with respect to the exclusion of a particular diagnosis, condition, therapeutic class, or medical specialty will be the responsibility of the P&T committee.

3. Step therapy

a. The Drug Utilization Review (DUR) board will be the advisory body responsible for development for Department step therapy protocols and prior authorization policies, in addition to their other responsibilities as defined in federal statute.

b. Current and future step therapy protocols will be reviewed and approved by the DUR board based on clinical evidence and best clinical practice guidelines. Modifications to the protocol will be accepted by the Department as the basis for development or revision of current and proposed step therapy protocols.

It should be noted that pharmaceutical representatives could not agree to nor discuss in detail their concerns regarding the use of supplemental rebates. That remains an area of disagreement as a number of manufacturers as well as the Pharmaceutical Research and Manufacturers Association are opposed to such programs.

Additionally, there was still strong interest on the part of several pharmaceutical representatives regarding a carve-out of all mental health drugs from a PDL, step therapy or prior authorization policies that the Department currently has in place or may develop in the future. However, as this concern did not relate to either S.B. 321 or S.B. 374, the issue was left for a separate discussion (AB 430 hearings). The Nevada-specific Texas Medication Algorithm Protocol (TMAP) will be reviewed by the DUR board as early as possible in the next fiscal year. DUR board recommendations or modifications for this protocol will be adopted by MHDS.

Again, we appreciate the opportunity to work with representatives of the pharmaceutical industry on our mutual concerns with these two bills. It is our belief that the broad terms of this letter of understanding could serve as the basis for removing these bills from further legislation discussion and as the basis for regulations to be adopted.

Finally, it is important to note this letter of understanding would not preclude the governor from taking necessary budgetary action to control health care spending in the event of reduced state revenue or increased costs of health care. Please feel free to call me if you have any questions or concerns.

Sincerely,

Michael J. Willden
Director

cc: Marybel Batjer, Chief of Staff, Governor's Office
Michael Hillerby, Deputy Chief of Staff, Governor's Office
J. Thomas Wood, Associate Director, State Government Affairs, Wyeth-Ayerst Pharmaceuticals
Susan Landwehr, Government Affairs, Eli Lilly and Company
Pete Ernaut, Managing Director, Jones Vargas
James Morgan, Associate Director, Government Affairs, Novartis
Carlos Brandenburg, Administrator, MHDS
Charles Duarte, Administrator, DHCFP
J. Patrick Coward, Government Affairs, Carrara Nevada