STATE OF CALIFORNIA
DEPARTMENT OF MANAGED HEALTH CARE

November 12, 2004

The Honorable Jackie Speier
Member of the Senate
State Capitol, Room 2032
Sacramento, Ca 95814

RE: Senate Insurance Committee Oversight Hearing

Dear Senator Speier:

Thank you for holding the Senate Insurance Committee hearing on the Department of Managed Health Care. I appreciated the opportunity to introduce myself to the Legislature and to discuss the important work that is carried out on a daily basis at the Department. As promised, here are our follow-up responses to several issues that were raised at the hearing.

1. Of the open enforcement cases, what are the categories of the cases, the actions taken, and the names of the Plans involved?

The table below describes all open enforcement cases by category as of September 30, 2004. The names of the Plans are not listed, as these cases are all currently under investigation.

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286 CASES CURRENTLY OPEN - As of September 30, 2004

ALLEGATION CATEGORY	NUMBER
ACCESS TO CARE: any allegations involving barriers to access to care	35
GRIEVANCE: any allegations relating to the grievance process	148
INDEPENDENT MEDICAL REVIEW (IMR): any allegations of violations of the independent medical review process	28
FINANCIAL: allegations relating to financial stability, filing financial statements, or maintaining tangible net equity	21
AB 1455: allegations relating to untimely claims payment, failure to pay interest or penalties, or unfair payment practices	23
MISC.: various other allegations of violations of the Knox-Keene Act (e:g. failure to file anti-fraud plans)	73
TOTAL ALLEGATIONS	**328**

2. How many enforcement actions has the Department brought for violations of AB 1455? Which Plans are involved? For cases under investigation, when will the information be made public?

Section 1371of the Knox-Keene Health Care Service Plan Act of 1975, as amended by AB 1455, is the primary mechanism in the Department's arsenal for resolving prompt payment issues. In general, section 1371 requires Plans to reimburse providers within 45 working days of submitting a complete claim. As of July 1, 2000, the Office of Enforcement has investigated 61 matters related to prompt payment issues involving Health and Safety Code section 1371. Of the 61 matters, 45 are closed and 16 remain open and under investigation.

We recently began tracking cases in connection with AB 1455, and found that of the 16 open cases, 12 are directly linked as violations of AB 1455. Of the 45 closed cases, 30 resulted in an enforcement action.

Total penalties collected were $812,200.

Enforcement actions taken include:

- 26 Letters of Agreement with the following Plans:
  - Sharp Health Plan
  - Managed Health Network
  - Human Affairs International of California
  - Heritage Provider Network, Inc.
  - Vista Behavioral Health Plans
  - Lifeguard, Inc.
  - Cigna HealthCare of California, Inc.
  - Merit Behavioral Care of California, Inc.
  - Pacific Union Dental, Inc.
  - One Health Plan of California, Inc.
  - Aetna Health of California, Inc.
  - Inter Valley Health Plan
  - SafeGuard Health Plans, Inc.
  - ValueOptions of California, Inc.
  - Western Dental Services, Inc.
  - Access Dental Plan
  - Molina Healthcare of California
  - Health Net of California, Inc.
  - Cigna Behavioral Health of California, Inc.
  - Western Health Advantage
  - Santa Cruz-Monterey Managed Medical Care
  - Alameda Alliance for Health
- One stipulated settlement agreement with WATTS Health Foundation, Inc.
- One conservator for WATTS Health Foundation, Inc.
- One miscellaneous court order against WATTS Health Foundation, Inc.
- One accusation filed against Sharp Health Plan

The information regarding any Plan under investigation will be made public if and when enforcement action has come to a resolution.

3. With respect to the Independent Medical Review (IMR) process, can the Department legally require Plans to change their practices if trends are noticed in denying or modifying care that have been later overturned during IMR? What is the Department's legal authority, and is there any other power the Department can assert in reforming Plan behavior?

The Department has clear authority to take action if a Plan has repeatedly failed to act promptly and reasonably to resolve grievances associated with a denial or modification of medically necessary health care services. Section 1374.34(e) requires the Director to perform an annual audit of IMR cases for both educational purposes and to determine whether the Department should undertake any investigative or enforcement actions. Under section 1368.04, the Department can assess penalties if it concludes that the Plan has failed to reasonably and promptly investigate and resolve grievances, either knowingly or with a frequency that establishes a general business practice.

A pattern of overturned medical necessity denials could be evidence that the Plan's medical policies do not reflect appropriate clinical principles, or that the Plan's denial and grievance processes have not adequately considered the specific medical needs of the enrollee.

Section 1363.5 requires Plans to develop medical criteria and guidelines that are consistent with sound clinical principles and processes, and that they are evaluated and updated annually. IMR results are incorporated into the review and assessment of medical policies. For example, Plans have reported they have significantly modified their protocols for requests for bariatric surgery consultations and have increased the types of surgical bypass procedures that will be covered by a Plan.

With very few exceptions, most disputes resolved through the IMR process arise from(1) reasonable differences of medical opinion about various treatment options, (2) questions regarding treatments for medical conditions that are in the process of becoming generally accepted, or (3) close questions of coverage and medical necessity. In such cases, the Department encourages Plans to review overturned IMR decisions as part of their quality assurance or medical policy processes. Additionally, a synopsis of decisions is available on the Department's website so that other Plans can consider the outcome reviews as they evaluate and review their medical policies. This resource enables all Plans to benefit from IMR decisions. Further, a meeting with health plan medical directors was held recently to discuss the IMR process and address any questions and enforcement issues that had arisen.

4. What are the criteria used to determine whether the Department will hold a public hearing?

Health and Safety Code section 1346(a)(5) gives the Director discretion to determine whether a public hearing will be held. The Department may determine the need for a public hearing on any topic pertaining to managed health care regulation, with or without a public request for a meeting. According to Government Code section 11346.8, the Director must meet specific notice and other procedural requirements when holding a hearing. Although current law and regulations do not specify any particular criteria to use when determining the need for a hearing, I have developed the following standardized criteria to use when deciding whether a public hearing is appropriate:

- Whether the proposal has the potential to deleteriously impact Plans, providers, subscribers, enrollees, or Californians generally, and the nature, scope, and significance of any such impact;
- The likelihood that a hearing would provide additional or more fully elaborated criteria that would need to be satisfied to achieve a sound decision;
- The likelihood that a hearing would help to assure identification of all relevant legal issues raised in the proposal;
- The likelihood that a hearing would provide additional facts or opinions relevant to a decision whether to approve the filing, including any conditions or undertakings to impose on the approval;
- The likelihood that a hearing would provide a greater depth or scope of understanding of the potential short-term and long-term results or ramifications of an approval, with or without conditions;
- Whether any stakeholder(s) in managed care – Plans, providers, employers or consumers – hold strong views on any of the foregoing factors;
- Whether the Department could devote sufficient time and energy to a hearing to maximize its value:

5. Are Plans complying with the osteoporosis-screening mandate? Does the Department have any data about osteoporosis-screening complaints?

At this time, the Department does not have any reason to believe that Plans are not complying with the osteoporosis-screening mandate.

A search of the Department's complaint database showed a total of 13 consumer complaints relating to osteoporosis over a 2.5 year period. In reviewing the data on these cases, the Department did not identify evidence of Plan non-compliance with the mandate for coverage provided under Health and Safety Code section 1367.67.

Additionally, a search of the Department's IMR database identified 13 separate cases involving denials of coverage, on the basis of medical necessity, for services related to diagnosis, treatment, and appropriate management of osteoporosis. Out of 13 completed IMRs, ten Plan denials (77%) were upheld, and three Plan denials (23%) were overturned by the review organization. In addition, in three cases, the Plan reversed an earlier denial prior to completion of the IMR.

The great majority of disputes involve (1) medical necessity, specifically, and legitimate differences of opinions concerning screening intervals, and (2) the type of testing that is indicated as a first-line screen, and the risk factors needed to support testing at a level above the usual frequencies and scope. Such disputes do not indicate non-compliance with the Knox-Keene Act because the Act and regulations do not prescribe specific criteria for osteoporosis testing, but allow Plans to develop their own clinical guidelines, within certain parameters.

In addition, considering evidence-based criteria, there is inadequate evidence to support a mandate of broad-based population "preventive health" osteoporosis screening without consideration of individual risk factors and age, as reflected in the recommendations from the United States Preventive Services Task Force (USPSTF). A leader in the field of evidence-based guideline development, the USPSTF recommends that women aged 65 and older be screened routinely for osteoporosis. In addition, the USPSTF recommends that routine screening begin at age 60 for women at increased risk for osteoporotic fractures. But there is insufficient evidence to mandate exact risk factors that should trigger screening at earlier ages.

6. What are the trends in filing material modifications - what types of filings? How many are for higher co-pays - what levels? Exclusions and limitations?

Plans are currently searching for ways to offer more affordable products to employers in light of the continuing rise in premium rates over the past three years. The bifurcated regulation of Preferred Provider Organization (PPO) products in California has and will continue to exacerbate cost-sharing trends. In the main, the Plans have turned to the Department of Insurance (DOI) for quick approvals of PPO products that feature greater consumer co-insurance contributions. These products have been very competitive in the marketplace over the past few years and have gained increasing market share. Outside California, the PPO is the most pervasive health insurance product across the country.

Although Health Maintenance Organizations (HMOs) are still the prevailing form of health care coverage in California, the number of enrollees has been in a small but appreciable decline for the past three years, and PPO membership has grown substantially during that time. The projected popularity of high-deductible products that qualify for health savings account tax benefits will increasingly marginalize the competitiveness of comprehensive benefit products with first-dollar coverage. The recent clearance of the Anthem-Wellpoint merger sets the stage for an accelerated incursion of such products, as Anthem's current product line promotes these products. The Department has had to acknowledge the realities of the marketplace and attempt to ensure the survival of quality health products and systems such as Kaiser by allowing co-pay and deductible increases, while requiring monitoring of the impacts of such increases. This is not a popular move with staff or consumers, but it is the necessary leadership for the current market.

Plans file proposed changes to their co-payments, deductibles, and out-of-pocket maximums as amendments, rather than as material modifications to their Knox -Keene licenses. In calendar year 2003, the Plans filed a total of 1,840 changes to their evidences of coverage for Plan products. The specific trends in product filings with the Department reflect increasing co-pays, deductibles, and out-of-pocket maximums, in varying combinations. Kaiser is experimenting with a new HMO product approved by the Department last year that features a $1,000 deductible. It is primarily offering the product in the individual subscriber market. The Department anticipated a large number of filings on the new high-deductible Plan products sanctioned under H.R. 1, the federal law permitting health savings accounts, but to date the Department has received only one filing -- from Kaiser. This Kaiser filing is similar to last year's high-deductible product, but with a health savings account component.

The other Plans have either licensed products with minimal hassle under DOI or have struggled to find a way to make a high-deductible product fit within the delegated care model utilizing large provider groups. No plan that contracts with large medical groups has found a solution to the problems posed in collecting and tracking the deductible amounts at the provider level in a capitated setting. It may be that high-deductible products are only feasible in the discounted fee-for-service model of the PPO world. Time will tell, but the Department will play a proactive role.

Given the administrative problems in implementing high-deductible HMO products, some Plans have tried other alternatives for lowering premiums. One approach included a lower-cost provider network. PacifiCare began marketing a narrow-network traditional HMO product that costs approximately seven percent less in annual premium rates in the large group market. PacifiCare has advised the Department that the demand for the product is weak.

In contrast, PacifiCare offers a DOI-approved PPO product, the Signature Freedom PPO. It is configured as a high-deductible product and is attracting 5,000 new subscribers a month. This product features a Plan-funded $1,000 spending account and is offered in both group and individual subscriber forms.

The volume of material modification filings is driven by industry trends and legislative changes. The deadline for filing continuity-of-care policies was March 31, 2004, which significantly increased the number of filings for the second quarter of 2004. The most prevalent material modifications are corporate changes by the Plans, including mergers, stock purchases, and name changes. Increases and decreases to service areas, including the withdrawal of products from the market, were also common. In addition, Plans may need to file material modifications because of legislative and regulatory changes to the Knox-Keene Act and its implementing regulations.

From January 2003 through June 2004, 145 orders were issued on material modification filings. These filings fall into several broad categories:

- License Surrender: Requests for formal surrender of a Knox-Keene license by a licensee.
- Service Area Change: These filings reflect increases or decreases in a Plan's service area, which includes the geographic area served, as well as changes to products. (An example of a service area change would be a filing for authorization to withdraw a product from the market.)
- Network Change: A Plan must file a material modification for a change in a provider network that encompasses more than ten percent of providers in a given geographic area.
- New Plan Product: These are filings by Plans for authorization to introduce an entirely new Plan product design.
- Benefit Exclusion/Limitation: This category includes filings for authorizations to exclude certain classes of drugs, for example, infertility drugs.
- Legislative Mandates: These are filings by Plans to comply with new regulatory and legislative changes; the most recent example is the continuity-of-care legislation.
- Corporate: Examples of changes that necessitate a material modification filing include stock purchases, name changes, mergers and sales.

	Approved	Disapproved	Withdrawn	Total
License Surrender	13			13
Service Area Change (Geographic or Product)	23	1	1	25
Network Change	5		1	6
New Plan Product	9	1	3	13
Benefit Exclusion/Change	14		2	16
Legislative Mandates	30		2	32
Corporate	30	2	1	33
Totals	124	4	10	138

7. What Plan has the highest out-of-pocket cost? What is the cost?

At present, the Plan with the highest out-of-pocket maximum is PacifiCare. The Department allowed this filing in May 2001, and permits a $5,000 out-of-pocket maximum on enrollee co-payments. The product does not have a deductible. PacifiCare sells this product in the large group marketplace (groups of 51 or more enrollees). PacifiCare advised the Department recently that it intends to submit a new product filing that features a fifty percent co-pay structure that will accrue to the $5,000 out-of-pocket maximum limit. There will not be a deductible. PacifiCare anticipates that this product could be marketed with the premium prices at twenty percent less than the current traditional HMO product.

8. How many enforcement actions were taken as a result of IMR cases? What were they? What Plans were involved?

IMR Resolution Charts

IMR statute became effective January 1, 2001

2001			
Health Plan	**Code Section**	**Issue**	**Penalties Collected**
Kaiser	1374.30	Delay in obtaining IMR	$5,000
Kaiser	1374.30	Failed to advise of right to IMR	$5,000
Total: 2			**$10,000**

2002			
Health Plan	**Code Section**	**Issue**	**Penalties Collected**
Blue Cross	1374.30	Failed to include IMR application	$5,000
Cigna	1374.30	Failed to include IMR application	$7,500*
Cigna	1374.3, 1374.30	Delay in submitting medical records to CHDR	$5,000
Health Net	1374.30	Failed to advise of right to IMR	$2,500
Health Net	1374.30	Failed to advise of right to IMR	$2,500*
PacifiCare	1374.30	Failed to advise of right to IMR	$10,000*
Kaiser	1374.34	Failed to implement IMR	$100,000
Kaiser	1374.34	Failed to implement IMR	Cease and Desist order issued
Total: 8			**$132,500**

*Also contains grievance violations.

2003			
Health Plan	**Code Section**	**Issue**	**Penalties Collected**
Health Net	1374.34	Failed to implement IMR	$140,000
Sharp	1374.30	Failed to advise of right to IMR	$ 35,000*
Total: 2?			**$175,000**

*Also contains grievance violations.

2004			
Health Plan	**Code Section**	**Issue**	**Penalties Collected**
Blue Cross	1374.30	Failed to include IMR application	$5,000*
Blue Cross	1374.34	Prolonged IMR process	$50,000
PacifiCare Behavioral	1374.30	Failed to include IMR application	$7,500*
PacifiCare	1374.30	Failed to include IMR application	$7,500*
Total: 4			**$70,000**

*Also contains grievance violations.

Total IMR Cases: 16	**Total Penalties Collected: $387,500**

9. Please describe the history of the "Dobberteen" letter. When was it first issued, and was it in fact a response to emergency room doctors who threatened to balance bill?

Below is the chronology of the "Dobberteen" letter:

a) In early May 2003, Amy Dobberteen, Staff Counsel in Enforcement, received a call from Dr. Miles Riner, an emergency physician. A lengthy conversation took place, during which the topic of balance billing was discussed. This conversation took place while the AB 1455 (2000) regulations were being written and were noticed for public comment. Dr. Riner stated that as a result of the Department agreeing to take out specific language from the regulations prohibiting emergency physicians from balance-billing enrollees, the Department could no longer state that emergency physicians were prohibited from balance billing.

b) Dr. Riner sent an email to Ms. Dobberteen with attachments, discussing the removed language. (Attached as Exhibit A)

c) Ms. Dobberteen responded by email thanking Dr. Riner for his information, and stating that the Department's position was that balance billing by emergency physicians was still improper. (Attached as Exhibit B)

d) Thereafter, James Randlett, President of the California chapter of the American College of Emergency Physicians, sent Ms. Dobberteen an email requesting an explanation of the Department's position against balance billing. (Attached as Exhibit C)

e) Ms. Dobberteen responded to Mr. Randlett informing him that a formal response would be forthcoming. (Attached as Exhibit D.)

f) On May 12, 2003, Ms. Dobberteen sent a letter to Mr. Randlett explaining that due to an implied-in-law contract theory, balance billing violates the Knox-Keene Act. This is the letter now commonly referred to as "the Dobberteen letter." (Attached as Exhibit E)

g) On July 2, 2003, a follow-up letter was sent to Mr. Randlett explaining that a "reasonable and customary" value must be paid for medical services. (Attached as Exhibit F)

h) In September 2003, the Department proposed an emergency regulation prohibiting balance billing. This proposed regulation was not adopted. (Attached as Exhibit G)

i) In December 2003, a Los Angeles trial court issued a decision in Prospect Health Source Medical Group v. St. Johns Emergency Medicine (Super. Ct. Los Angeles County, 2003, No. BC300850). (Attached as Exhibit H) Despite the fact that no enrollees were present in this lawsuit to argue the improper conduct of balance billing, the court found that the position stated in the Dobberteen letter was not dispositive. The court refused to not read Health and Safety Code section 1379 so broadly as to include a contract implied-in-law. This decision is not controlling because trial court decisions have no precedential value, meaning that they are not controlling in subsequent cases based upon a similar legal issue. In order to be a precedential decision, the decision must be made at or above the Court of Appeal level.

10. How will the Department's undertakings for the Anthem/WellPoint merger ensure that quality of care improves?

The Order of Approval to the Notice of Material Modification involving the change of control of Blue Cross of California (Blue Cross) arising from the merger of WellPoint into Anthem is subject to certain conditions or "undertakings." These undertakings oblige Blue Cross to establish a program to improve quality assurance, require certain actions by Blue Cross regarding specific quality-of-care issues, and authorize the Department to inspect/audit the compliance with these undertakings at Blue Cross' expense. The undertakings are co-signed by Anthem and Blue Cross' prospective parent to ensure that all parties who may ultimately control Blue Cross are legally bound to the obligations.

Blue Cross has undertaken to implement the Patient Advocate Program, which is a comprehensive program to further improve Blue Cross' quality of care. One of the goals of the Patient Advocate Program is to improve Blue Cross' "one star" scores as described in the Quality of Care Report Card (2003-2004) issued by the California Office of the Patient Advocate (OPA). The "one star" areas where Blue Cross is expected to improve the quality of care include:

- Early identification of health care issues and preventive care
- Screening women for breast cancer
- Immunizing children
- Appropriate medication for heart attacks
- Checking and controlling cholesterol for enrollees with serious heart problems

If Blue Cross fails to achieve improvement in any of its "one-star" scores by the time of the next OPA Report Card (or receives a new "one-star" score), it will provide a report, authored by an independent expert, to the Department, explaining how it will improve its score. Blue Cross will then implement the recommendations and furnish a supplemental report regarding the progress of any corrective actions.

Blue Cross must improve any low scores received on Health Plan Employer Data and Information Set ratings. The quality-of-care areas needing improvement include disease prevention, screening, health surveillance, and intervention.

In addition to improving *identified* issues in delivering quality of care, the Patient Advocate Program will include *new* health care initiatives concerning mental health, obesity, Chlamydia screenings, and the use of antibiotics. The mental health initiative involves improving identification and treatment of depression, including follow-up of any Blue Cross patient admitted with a diagnosis relating to mental health or disease. The initiative for Chlamydia screening is to improve the percentage of members appropriately screened and treated for Chlamydia. Thus, quality of care should improve as more health issues are addressed.

Unlike the current pay-for-performance program spearheaded by the California Association of Physician Groups (in which Blue Cross participates along with other Plans) where professional provider groups are given incentives to improve care, this Blue Cross Patient Advocate Program will provide incentives to improve the quality of care delivered by health care practitioners not affiliated with capitated physician groups.

As part of the signed undertaking, Blue Cross acknowledged receipt of the final report of a routine medical survey and agreed to take all steps necessary to resolve outstanding issues. Many of those issues involve quality of care. Some examples of identified deficiencies include sufficiency of Blue Cross staff to investigate quality of care complaints, documentation showing that quality-of-care issues have been identified and corrective action taken, and criteria to review utilization management decisions.

In addition, the Plan agreed to retain an independent expert to evaluate whether the issues identified in the medical survey report occurred during the timeframe encompassed by the report through the effective date of the merger. If issues are identified, Blue Cross undertook to implement recommendations of the expert to resolve those issues. Blue Cross agreed to furnish a copy of the recommendations and the corrective actions to the Department. In this way, any improvements needed to improve quality of care would be implemented prior to their being identified by the Department during the next routine, retrospective medical survey. In addition, through Blue Cross' self-reporting, the Department will know what areas to focus on in evaluating correction of deficiencies. (The Department will be able to concentrate its oversight on *evaluating* the appropriateness of the corrective action, versus *identifying* the deficiency.)

Blue Cross also agreed to resolve issues in a non-routine medical survey of its Behavioral Health Division. Although Blue Cross is obligated to correct the deficiencies identified in the survey, regardless of the merger, by having these deficiencies subject to an undertaking, Blue Cross is subject to an additional verification process. Pursuant to the undertakings, the Department need not give Blue Cross notice of a routine survey, nor does the Department need to consider its budget when assigning Department personnel for a survey, since the oversight expenses will be directly reimbursed by Blue Cross.

Finally, Blue Cross agreed to pay for all costs arising from the Department's actions to verify that Blue Cross will fulfill its performance obligations. Even if there is a budget shortfall, the Department will not have to postpone or restrict its auditing activities to verify compliance with these quality initiatives. The ability to perform non-routine audits provides the Department with more flexibility and ensures timely feedback. In addition, with the specter of frequent non-routine examinations, it is theoretically more likely that Blue Cross will maintain these quality-of-care initiatives as one of its highest priorities.

Again, I thank you for your interest in the Department of Managed Health Care, and welcome the opportunity to respond to your concerns. I hope that our responses to your questions are helpful to you as we work together to ensure that Californians receive high quality health care and cost-effective regulatory oversight.

Sincerely,

Lucinda A. Ehnes, JD
Director
Department of Managed Health Care

cc: Brian Perkins, District Representative
Soren Tjernell, Consultant

Matter ID# 2004-0274