

HMOs & Health Plans

Winter 2001 Volume 4 Issue 2

A Publication of the American Health Lawyers Association HMOs and Health Plans Substantive Law Committee

TABLE OF CONTENTS

The Patient Bill of Rights - An Analysis of the Senate and House Bills
David Ermer, Esq.
Robert Iadicicco, Esq.1

Notes from the Editor
Margit Nahra, Esq.8

Medicaid at the Crossroads: Medicaid Managed Care Under the Bush Administration
Jeffrey Layne, Esq.
Lori-Ann Bellan, Esq.9

The Debate on a Possible Switch from Prescription to Over-the-Counter Status for Second-Generation Antihistamines
Karen Weiss13

Recent OIG Advisory Opinions Address Health Plan Arrangements
Robert Rabecs, Esq.16

Databanks: They're Not Just for Hospitals Anymore
Alicia Palmer, Esq.20

The Patient Bill of Rights – An Analysis of the Senate and House Bills

David M. Ermer, Esquire
Robert G. Iadicicco, Esquire
Gordon & Barnett
Washington, DC

The tragic events of September 11 have had an enormous impact on Federal legislative priorities. One example is the almost total disappearance of any movement toward enactment of "Patient Bill of Rights" (PBR) legislation covering individuals enrolled in health plans (participants). Before September 11, the Senate Democrats, who were newly in control, made PBR enactment their number one priority. The Bush Administration and the House Republican leadership also placed a high priority on this measure. Not surprisingly, earlier this year the Senate and the House passed versions of the PBR that share many common features but diverge dramatically on the issue of patient litigation against health plans (HPs). In view of the war against terrorism and the recessionary economy, it is uncertain how much time will pass before Congress turns its attention back to this legislation. This unexpected pause provides an opportunity to analyze the Senate and House versions of the PBR.

On June 29, 2001, the Senate passed S. 1052, entitled the "Bipartisan Patient Protection Act" (the Senate Bill or SB)),

and about six weeks later, on August 8, 2001, the House of Representatives passed H.R. 2563, which is based on the Senate Bill and bears the same title (the House Bill or HB). Both PBR bills, if enacted, would establish standards for utilization review (UR), initial claims determinations, internal and external review of claim denials, patients' access to care and information, and the doctor-patient relationship (the patient protections). In addition, the Bills would expand the ability of patients to sue their HPs.

As discussed in more detail below, the most significant differences between the Bills concern:

- The availability of civil remedies to participants under the Employee Retirement Income Security Act (ERISA), 29 U.S.C. § 1001 et seq., for non-medically reviewable HP decisions, and State law causes of action for medically reviewable HP decisions.
- The application of the legislation to federal healthcare programs, such as Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Program, and the Department of Veteran Affairs healthcare system.
- The House Bill provisions authorizing Association Health Plans and amending the Federal law governing Medical Savings Accounts (MSAs) that are not included in the Senate Bill.

- The Senate Bill provision that prohibits HPs from establishing enrollment restrictions or adjusting their rates based on genetic information that is not included in the House Bill.

Much attention and debate has been focused on the differences between the Bills, but what has largely gone unnoticed is that the patient protection provisions in both Bills are almost entirely identical. Though many HPs have adopted many of the patient protections contained in these Bills, few, if any, have adopted all of them.

The following is a section-by-section analysis of the patient protection and civil action provisions in the House and Senate Bills. Because the House Bill is based on the Senate Bill, both bills share many provisions verbatim right down to the Section number. Shared sections are indicated with the signal "SB/HB § –."

- I. Utilization Review, Claims, and Internal and External Appeals
 - A. Utilization Review Activities

SB/HB § 101 establishes requirements for UR programs. HPs must develop written policies and procedures that govern all UR program aspects. For healthcare services that have been preauthorized, an HP may not revise or modify the UR standards, criteria, or procedures during retrospective review of



Leading Health Law to Excellence
through Education,
Information, and Dialogue

HMOs and Health Plans © 2001 is published by the American Health Lawyers Association. All rights reserved. No part of this publication may be reproduced in any form except by prior written permission from the publisher. Printed in the United States of America. "This publication is designed to provide accurate and authoritative information in regard to the subject matter covered. It is provided with the understanding that the publisher is not engaged in rendering legal or other professional services. If legal advice or other expert assistance is required, the services of a competent professional person should be sought."
—from a declaration of the American Bar Association

Continued from page 1

any procedures, treatments, and services delivered to the participant during the same course of treatment. SB/HB § 101 also:

- 1) Requires periodic evaluations of samples of denied claims for clinical appropriateness;
- 2) Provides that UR staff be qualified, appropriately trained, and accessible by toll-free telephone during normal business hours and be able to receive and respond promptly to calls made during other hours;
- 3) Prohibits compensation to UR staff or contractors that encourages claim denials; and
- 4) Limits the frequency of UR performed to no more than what is reasonably required to assess whether the services are medically necessary and appropriate.

B. Initial Claims and Prior Authorizations

SB/HB § 102 creates standards governing HP procedures for initial claims and prior authorization determinations. The Bills define “prior authorization” as the process of obtaining prior approval from a HP for the provision or coverage of medical services.¹

Type of Determination	Deadline for Making Determination
Prior authorization (PA)	No later than fourteen days from the date the HP receives the information necessary to make a determination and in no case later than twenty-eight days from the date the claim is received
Urgent PA ²	Within seventy-two hours of receiving the request
Concurrent/Ongoing Care Review	If the HP determines that the treatment should be terminated or reduced, the HP must notify the participant by telephone and in printed form with sufficient time to allow for an internal appeal of the determination before the termination or reduction takes effect
Post-service claims	Within thirty days after receiving the necessary information, or within sixty days from the date the claim is received, whichever is earlier

In the case of claim denials, HPs must provide written notice within two days of the determination, including the specific reasons for the determination, the procedures for obtaining additional information regarding the determination, and a notification of appeal rights, including instructions on how to initiate an appeal.

C. Internal Appeals of Denied Claims

SB/HB § 103 establishes standards governing internal appeals of claim denials. Health plans must give participants the opportunity to appeal a claim denial to the plan. Participants have a period of not less than 180 days beginning on the date of the denial to file the appeal. Participants and their treating healthcare professionals must provide plans access to information necessary to make a determination within five days of the request for such information. The participant’s or healthcare professional’s failure to comply with this requirement shall not excuse the HP from making a determination as soon as possible.

Type of Determination	Deadline for Making Determination on Appeal
Urgent PA	Within seventy-two hours of receiving the appeal
PA	No later than fourteen days from the date the HP receives the information necessary to make a determination and in no case later than twenty-eight days from the date the appeal is received
Concurrent/Ongoing Care Review	The HP must provide its determination on the appeal as soon as possible, with sufficient time prior to the termination or reduction to allow for an independent external appeal to be completed before the termination or reduction takes effect
Post-service claims	Within thirty days after receiving the necessary information, or within sixty days from the date the claim is received, whichever is earlier

Reviews of appeals of claim denials that involve “medically reviewable decisions” must be made by a physician (or for services provided by a non-physician health professional, by a non-physician health professional of the same or similar specialty) who is licensed by the State in which the service was provided or rendered, and who was

not involved in the initial determination.³ Written notice of the determination on appeal must be provided within two days of making the decision. The notice should include a summary of the clinical evidence used to make the determination, the procedures for obtaining additional information, and notification of the right to an independent external review.

D. Independent External Appeal Procedures

Under SB/HB § 104, HPs must provide participants access to an independent external review of denied claims. Participants must file a request for independent external review within 180 days of the date they receive notice of the HP's denial under the internal appeals process. The HP may charge a filing fee of up to \$25, but failure to pay the fee does not prevent the consideration of the request for review, and if the independent external review determination reverses the denial the filing fee is refundable.

Upon the filing of a request for review, HPs must immediately refer the request and provide the plan's initial decision (including the reason for denial) to a qualified external review entity. The external review entity must screen the request to ensure the claim denial is eligible for independent medical review. Only claim denials that involve "medically reviewable decisions" are eligible.

Type of Appeal	Deadline for External Review Decision
Urgent PA	Within seventy-two hours after receipt of review request
PA	Within fourteen days of receiving the necessary information and no later than twenty-one days after the date the request for external review is received
Concurrent/Ongoing Care Review	Twenty-four hours after receipt of the request
Post-service claim	Within thirty days after receiving the necessary information or within sixty days after receiving the request for external review, whichever is earlier

An independent medical reviewer's decision is binding on the HP. If the independent medical reviewer's determination reverses or modifies the denial, the reviewer must include a timeframe within which the HP must comply with the determination. If the HP does not comply with the determination within the required timeframe, the participant may acquire the items or services involved from any provider. In such cases, the HP is required to pay the total costs for

such items or services, regardless of any plan limitations that may apply to the coverage for such items or services, or face civil action to recover the amount.

HPs are subject to a \$10,000 civil penalty in any case in which the HP fails to provide treatment or coverage in accordance with the independent external review determination. In addition, HP officials who refuse to authorize the required coverage or treatment are subject to a \$1,000 per day civil penalty, and a penalty of up to \$500,000 if there is clear and convincing evidence the official has a pattern or practice of repeatedly refusing to comply with such determinations.

Contracts between HPs and qualified external review entities may not include compensation that is contingent on any decision rendered by the entity or by any independent medical reviewer.

11. Access to Care

Choice of Healthcare Professional

SB/HB § 112 requires that if an HP requires, or provides for, the designation of a participating primary care provider, then each participant must be permitted to designate any available participating primary care provider.. HPs also must permit each participant to receive specialty care, pursuant to appropriate referral procedures, from any available qualified participating healthcare professional.

Emergency Care

SB/HB § 113 prohibits HPs that provide emergency services coverage from imposing PA requirements on such coverage and may not limit such coverage to participating providers.⁴ The section defines "emergency medical condition" and "emergency ambulance services" using the "prudent layperson" standard.

Specialists Generally

SB/HB § 114 requires HPs to ensure that participants receive timely access to specialized care when such care is covered under the plan. If a participating specialist is not available, then the HP must provide coverage of such care by a nonparticipating specialist at no additional cost to the participant. The provision would permit HPs to require an authorization to obtain coverage for specialty care for an appropriate duration of time or number of referrals, and require a treatment plan for referrals to a specialist for the treatment of ongoing special conditions.

Obstetrical and Gynecological Care

SB/HB § 115 prohibits HPs from requiring its female participants to obtain a referral or authorization to receive coverage of obstetrical or gynecological care provided by a participating professional who specializes in such care.

Pediatric Care

SB/HB § 116 requires HPs that require or provide for the designation of a participating primary care provider for a child to permit

Continued on page 4

Continued from page 3

the designation of a physician who specializes in pediatrics as the child's primary care provider if the provider participates in the HP's network.

Continuity of Care

Under SB/HB § 117, when a contract between a HP and a treating healthcare provider is terminated for reasons other than failure to meet applicable quality standards or fraud, the HP must offer participants who are "continuing care patients" the right to elect continued transitional care from the terminated provider.⁵ In general, the continued transitional care period is limited to 90 days after the date the HP sends the continuing care patient a notice of the termination and their right to elect continued transitional care. However, the HP may condition continued transitional care on the terminated provider agreeing to certain terms and conditions, including accepting reimbursement at the rate applicable prior to the start of the transitional period, adhering to the quality assurance standards of the plan and providing necessary medical information to the plan, and otherwise adhering to the plan's policies and procedures.

Coverage of Prescription Drugs from a Formulary

SB/HB § 118 requires HPs that limit prescription drug coverage by using a formulary to ensure the participation of physicians and pharmacists in developing and reviewing the formulary; provide for the disclosure of the formulary to providers; and allow for coverage exceptions when a non-formulary drug is deemed to be medically necessary, and, in those cases apply the same cost-sharing requirements that would have applied if the drug was covered under the formulary. In addition, the provision would prohibit HPs that cover prescription drugs and medical devices from excluding from such coverage as experimental/investigation any drug or device usage found in the current Food & Drug Administration authorized labeling, without regard to any applicable post-marketing requirements.

Coverage for Individuals Participating in Approved Clinical Trials

SB/HB § 119 prohibits HPs from denying participants with life-threatening or serious illnesses for which there is no standard treatment the option to effectively participate in approved clinical trials. Section 119 further prohibits HPs from either denying coverage for routine patient costs connected with such a trial or discriminating against a participant based on the participant's participation in a clinical trial. HPs may require the participant to engage in the trial through a participating provider involved in the trial. If the participant participates in the clinical trial through a nonparticipating provider, the HP must pay the provider at the rate the plan would normally pay a participating provider for comparable services.

Required Coverage for the Treatment of Breast Cancer

Under SB/HB § 120, HPs are required to ensure that inpatient coverage for the treatment of breast cancer is provided for a time period determined by the provider, in consultation with the patient, to be

medically necessary following a mastectomy, a lumpectomy, or a lymph node dissection. HPs also must provide full coverage of secondary consultations by specialists in the appropriate medical fields to confirm or refute a diagnosis of cancer. If the attending physician certifies in writing that services necessary for such secondary consultations are not sufficiently available from specialists within the HP's network, the HP must cover the necessary services provided by any other specialist selected by the attending physician at no additional cost to the participant. HPs may not offer incentives to providers designed to encourage them to limit length of inpatient stays or referrals for secondary consultations.

III. Access to Information

Patient Access to Information

SB/HB § 121 requires HPs to provide participants with extensive information regarding plan benefits and other plan policies at the time of enrollment and on an annual basis thereafter in conjunction with election periods or, if the HP does not have election periods, the beginning of the plan year. Any reduction in benefits must be reported to participants thirty days before the reduction takes effect.

Protection of Genetic Information

SB § 122 prohibits HPs from denying eligibility or adjusting premium rates based on predictive genetic information about a participant or requesting or requiring predictive genetic information that is not needed for diagnosis, treatment, or payment. HPs must also post or provide written notice of the plan's policies regarding the confidentiality of predictive genetic information, including a description of the individual's rights, the procedures established by the plan for the exercise of those rights, and a description of the right to obtain a copy of the notice of confidentiality practices.

There is no such provision in the House Bill.

IV. Protecting the Doctor-Patient Relationship

Prohibition of Interference with Certain Medical Communications

SB/HB § 131 prohibits and makes null and void any provision in a contract between a HP and a healthcare provider that would prohibit the provider from advising participants about their health status or the medical care or treatment needed for their condition, regardless of whether the HP covers that care or treatment.

Prohibition of Discrimination Against Providers Based on Licensure

SB/HB § 132 prohibits HPs from discriminating with respect to participation or indemnification against any provider solely on the basis of the provider's State license or certification. The provision does not require HPs either to cover a particular benefit or service or to include in their network every willing provider who meets the terms and conditions of the plan. Our interpretation of this provision is that it would require HPs to pay any person who provides a covered service that is within the scope of his or her State license or certification. Currently,

HPs may limit the categories of providers who are eligible to receive payment for covered healthcare services.

Prohibition Against Improper Incentive Arrangements

SB/HB § 133 prohibits HPs from operating a “physician incentive plan” unless no specific payment is made directly or indirectly to a physician or physician group as an inducement to reduce or limit medically necessary services provided to a specific HP participant.⁶ In addition, if the physician incentive plan places a physician or physician group at substantial financial risk for services not provided by the physician or physician group, the HP must provide adequate and appropriate stop-loss protection for the physician or physician group.

Timely Payment of Claims

SB/HB § 134 requires HPs to mail or otherwise transmit payment on 95% or more of “clean claims” within 30 calendar days of receipt.⁷ In addition, if a HP fails to make a payment within thirty calendar days of receiving a clean claim, the HP must pay interest (at the rate used for purposes of 31 U.S.C. § 3902(a)) for the period beginning on the thirty-first day and ending on the date payment is made.

Anti-retaliation

SB/HB § 135 prohibits HPs from retaliating or discriminating against participants or healthcare providers for participating in the plan’s UR or grievance process (including an internal or external review or appeal process). The provision also prohibits HPs and any institutional healthcare providers that are HP participating providers from retaliating or discriminating against a healthcare professional who in good faith discloses information regarding care, services, or conditions affecting one or more participants to an appropriate public regulatory agency, an appropriate private accreditation body, or appropriate HP management personnel; or who initiates, cooperates, or otherwise participates in an investigation or proceeding of such an agency with respect to such care, services, or conditions.

V. Incorporation into Plan or Coverage Documents

SB/HB § 156 provides that the provisions concerning UR, claims, internal and external appeals, access to care, access to information, and protecting the doctor-patient relationship are deemed to be incorporated into and made part of HP contracts, and are enforceable under law as if directly included in the HP contract.

VI. Application to Group HPs and State & Local Governmental HPs

The preceding PBR protections are collectively referred to as title I. SB/HB § 201 requires group HPs covered under the Public Health Service Act (PHSA) to comply with title I. Similar to the Health Insurance Portability and Accountability Act, it also imposes that compliance requirement on any group health insurance coverage offered by a health insurance issuer.

SB/HB § 202 requires individual health insurance coverage to comply with title I.

SB/HB § 203 amends the PHSA to provide that a State may enter into an agreement with the U.S. Department of Health and Human Services (DHHS) delegating title I enforcement authority to the State. The State may then, if authorized under State law and consistent with the agreement, further delegate that authority to any department, agency, or instrumentality of the State. The authority to enforce the requirements of title I within any given State under § 203 is limited to non-Federal HPs. Federal HPs remain under Federal jurisdiction.

VII. Application of Patient Protection Standards to Federal Healthcare Programs

Under SB § 301, federal healthcare programs⁸ must comply with title I. In addition, the section provides that any individual who receives a healthcare item or service under a Federal healthcare program shall have a cause of action against the Federal Government under the sections 502(n) and 514(d) that the SB would add to ERISA, which are summarized below.⁹

In contrast, HB § 301 does not mandate the application of title I to federal healthcare programs, but rather expresses the “sense of Congress” that federal healthcare program participants should have the same rights afforded to participants and beneficiaries under other group HPs. The bill further expresses the sense of Congress that the President should require, by Executive Order, “the Federal official with authority over each Federal health insurance program, to the extent feasible, to take such steps as are necessary to implement” those rights and privileges, and that the General Accounting Office should, no later than one year after enactment, “submit to Congress a report on statutory changes...required to implement such rights and privileges in a manner that is consistent with the missions of the Federal health insurance programs and that avoids unnecessary duplication or disruption of such programs.”

VIII. Amendments to ERISA

Application of Patient Protections to ERISA

SB/HB § 401 amends ERISA by adding Section 714, Patient Protection Standards, which incorporates the title I protections into ERISA.

Amendments to ERISA Creating New Civil Remedies

The Senate Bill

SB § 402 would amend ERISA § 502, 29 U.S.C. § 1132, by adding subsection (n) that would establish federal civil remedies in cases not involving medically reviewable decisions. Specifically, it would allow participants to sue for economic and non-economic (but not exemplary or punitive) damages against a group HP fiduciary who fails to exercise ordinary care in making a decision regarding:

Continued on page 6

Continued from page 5

- Whether an item or service is covered under the plan;
 - Whether an individual is enrolled under the plan; or
 - The application of cost-sharing requirements or the application of a specific exclusion or express limitation on the amount, duration, or scope of coverage of items or services under the plan; and
- such failure is a proximate cause of personal injury to, or the death of, the participant.

The cause of action must not involve a medically reviewable decision, such as a decision based on a medical necessity or an experimental/investigational procedure determination. The provision also authorizes imposition of a civil assessment of up to \$5,000,000 if the plaintiff establishes by clear and convincing evidence that the defendant's alleged conduct exhibited bad faith and flagrant disregard for the plaintiff's rights.

The provision places the following limits on this cause of action:

- 1) A cause of action may not be maintained against a group HP sponsor or an employer maintaining the plan unless the employer or plan sponsor directly participated in the initial adjudication or internal appeal of the claim that is the subject of the cause of action. The provision further authorizes an employer or plan sponsor that does directly participate in the initial adjudications or internal appeals to transfer all its liability under 502(n) of ERISA to a designated decision-maker.
- 2) A cause of action does not arise where the denial concerns an item or service that has already been fully provided to the participant and the claim relates solely to the subsequent denial of payment for the provision of such item or service. However, the provision does state that this limitation does not prohibit a cause of action in such cases where the nonpayment results in the participant being unable to receive further items or services that are directly related to the item or service involved in the denial or that are part of a continuing treatment or series of procedures; prohibit a cause of action relating to quality of care; or limit liability that otherwise would arise from the provision of the item or services or the performance of a medical procedure.
- 3) The cause of action may only be brought after the exhaustion of the HP's initial claims adjudication and internal appeals process.
- 4) A statute of limitations bar is imposed three years after the date the plaintiff first knew, or reasonably should have known, of the personal injury or death resulting from the failure that is the subject of the claim; or the date on which the HP's initial adjudication and internal appeal of the claim is exhausted, whichever is later.

Section 402 would also amend ERISA § 514 (its broad state law preemption provision) to state that ERISA does not preempt any State law cause of action that would allow a participant of a group HP to recover damages resulting from personal injury or for wrongful death against any person if such cause of action arises by a medically reviewable deci-

sion. The provision would preempt any State law insofar as it provides for any punitive damages if the HP followed the sections covering the federal initial adjudication, internal appeal, and independent external appeal standards with respect to the claim that is the subject of the cause of action. The only exceptions from the preemption of punitive damages are (1) if the applicable State law provides (or has been construed to provide) for damages in an action for wrongful death which are only punitive or exemplary in nature; or (2) if the plaintiff establishes by clear and convincing evidence that conduct carried out by the defendant with willful or wanton disregard for the rights or safety of others was a proximate cause of the personal injury or death that is the subject of the action.

This provision places limits on the right to sue that are similar to the limits on the section 502(n) cause of action summarized above. First, a State cause of action may only be brought after the exhaustion of the HP's initial claims adjudication and internal appeals process and the independent external appeals process. Second, a State cause of action does not arise where the denial involved relates to an item or service that has already been fully provided to the participant and the claim relates solely to the subsequent denial of payment for the provision of such item or service. The exceptions from this limitation are the same exceptions that apply to the identical section 502(n) limitation. Finally, the same limitations that are placed on suits against employers and other plan sponsors under the section 502(n) cause of action also apply to State causes of action under 514(d) of ERISA.

The House Bill

The language in Section 402 of the House Bill differs significantly from the Senate bill. Participants would still be able to sue their HPs over medically reviewable claims denials in State courts, but State courts would be required to adjudicate those claims under new federal standards added to ERISA. If employers who sponsor HPs are named in a lawsuit related to a medically reviewable claims denial, they would be able to seek removal to a federal court. In lawsuits pertaining to non-medically reviewable claims denials, both employers and insurance companies named as defendants would be able to request removal to a federal court.

The House Bill also places caps on non-economic and punitive damages. Non-economic damages would be limited to \$1.5 million. Punitive damages would also be limited to \$1.5 million, and would only be available if the designated decision maker for the HP failed to comply with an independent medical reviewer's decision that the claim for benefits should have been granted. The Senate bill sets no caps on damages in state courts and allows unlimited economic and non-economic damages in federal court.¹⁰

Under both the House and Senate bills, these ERISA amendments would apply to acts and omissions (from which a cause of action arises) occurring on or after October 1, 2002.

Limitation on Certain Class Action Litigation

In Section 403 of both Bills, class actions under ERISA § 502 are limited to participants of a group HP established by one sponsor.

No action may be consolidated or joined with another class. However, in the Senate Bill, the provision does not go into effect until January 1, 2002, and applies to "all civil" actions filed on or after that date. The House Bill applies to "actions commenced" on or after August 2, 2001, as well as "civil actions which are pending... in which a class action has not been certified as of such date."

Limitations on Actions

SB/HB § 404 amends ERISA § 502 to place limitations on actions against group HPs. While an action may be filed for matters relating to UR or access to care (under Sections 101, 113, 114, 115, 118(a)(3), 119, or 120 of title I), such actions may not be class actions, and relief may only be provided for the benefits, items, or services denied to the individual participant or beneficiary involved (and for attorney's fees and the costs of the action, at the discretion of the court). No additional relief may be provided under this section, and no relief may be provided to anyone other than the beneficiary involved.

Cooperation Between Federal and State Authorities

SB/HB § 405 amends ERISA to provide that a State may enter into an agreement with DHHS delegating the authority to enforce title I to the States. The State may then, if authorized under State law and consistent with the agreement, further delegate that authority to any department, agency, or instrumentality of the State. The authority to enforce the requirements of title I within any given State under § 405 is limited to non-Federal HPs. Federal HPs remain under Federal jurisdiction.

Sense of the Senate Concerning the Importance of Certain Unpaid Services

SB/HB § 406 expresses the sense of the Senate that the court should consider the loss of a non-wage earning spouse an economic loss and that, rather than defining compensation for such a loss as "minimum services", the court should view such a loss in "terms that fully compensate for the true and whole replacement cost to the family."

IX. Severability

The Senate Bill and the House bill vary regarding the issue of severability. SB § 503 states that if any provision of the bill is found to be unconstitutional, then the rest of the law will remain unaffected. HB § 603(b) provides that "if any provision of section 503A, 503B, or 503C of [ERISA] (as inserted by section 131) or the application of either such section to any person or circumstance is held to be unconstitutional, section 502(n) of such Act (as inserted by section 402) shall be deemed to be null and void and shall be given no force or effect." Again, this disparity between the two bills deals specifically with the right to sue. Liability will no doubt continue to be a hotly contested issue in the crafting of a law that will be acceptable to both the House and the Senate.

X. Annual Impact Review

SB § 606/HB § 706 requires the Institute of Medicine (IOM) to submit a report to Congress not later than twenty-four months after the gener-

al effective date of the PBR and annually thereafter for the next four years concerning the impact of the PBR on the number of Americans with health insurance. If an IOM report determines that more than 1,000,000 individuals in the United States have lost their health insurance as a result of the PBR, section 402 (which expands the right to sue health plans) would be repealed on the date that is twelve months after the date on which the IOM report was submitted.

XI. Effective Dates

SB § 501 /HB § 601 requires group HPs governed by ERISA and the PHSA to comply with its provisions concerning utilization review, claims, internal and external appeals, access to care, access to information, and protecting the doctor-patient relationship (the patient protections) by the plan year beginning on or after October 1, 2002 (the general effective date).

Endnotes

- ¹ One example of a prior authorization process is a requirement by a HP that members must notify it of elective inpatient admissions and obtain the HP's preauthorization of the admission to receive coverage under the plan for the inpatient admission.
- ² Urgent PA is required when a healthcare professional certifies that a delay would seriously jeopardize the participant's life or health or his/her ability to maintain or regain maximum function.
- ³ Medically reviewable decisions are claim denials based on a lack of medical necessity and appropriateness or an experimental/investigational treatment determination, or denials otherwise based on an evaluation of medical facts.
- ⁴ Emergency services include maintenance care, post-stabilization care and emergency ambulance services in addition to a medical screening examination.
- ⁵ A continuing care patient is defined as a patient who is undergoing treatment for a complex and serious condition, is undergoing a course of institutional or inpatient care, is pregnant, is scheduled to undergo surgery, or is determined to be terminally ill.
- ⁶ Such a plan is defined as any compensation arrangement between a HP and a physician or physician group that may directly or indirectly have the effect of reducing or limiting services provided to the HP's participants.
- ⁷ Clean claims have no defect or impropriety, or particular circumstance requiring special treatment.
- ⁸ Federal healthcare programs principally include Medicare, Medicaid, TRICARE, the Federal Employees Health Benefits Program, and the Department of Veteran Affairs healthcare system.
- ⁹ In addition, SB § 301 states that each federal healthcare program shall be deemed to be a group HP; the Federal Government is deemed the plan sponsor of each federal healthcare program; and each individual eligible for benefits under a federal healthcare program shall be deemed to be a participant, beneficiary, or enrollee under that program.
- ¹⁰ The language in the House Bill can be interpreted in a way that significantly limits a patient's right to sue. While the Senate Bill states that a HP could be sued for damages if its failure to exercise ordinary care in making a health benefits decision was "a proximate cause" of a personal injury to or death of a beneficiary, the House Bill would only allow the patient to sue if the HP's decision was "the proximate cause" of death or personal injury. Under this language, health maintenance organizations (HMOs) would not be required to prove that they were not at fault, but only that someone else was also at fault, such as the provider or plan sponsor. By changing the article from "a" to "the," the House Bill would, technically, allow HPs to argue that they could not be held liable for the death of a cancer patient to whom care was denied or perhaps mismanaged, as the cancer itself would be "the" cause of death, not any decision the HP may or may not have made. While the issue has been described as "exaggerated" by some, sponsors of the Senate Bill have expressed a great deal of concern regarding the language.

NOTES FROM THE EDITOR

Margit H. Nahra, Esquire
Crowell & Moring LLP
Washington, D.C.

The events of the past three months have dramatically affected all of us, both personally and professionally. Yet in the midst of all the turmoil, I was struck once again by the willingness of our members and others serving the managed care industry to share their time and their expertise by writing articles for this issue of the HMOs and Health Plans newsletter. Thanks to their commitment, this fourth edition of the newsletter features in-depth analyses of such topics as the Patients Bill of Rights, recent developments in Medicaid managed care, and WellPoint Health Networks Inc.'s petition to have certain prescription drugs switched to over-the-counter status. On behalf of the SISLC leadership, I would like to thank all of our authors for making the newsletter possible.

Nor shall the SISLC's efforts to keep you informed stop with the newsletter. Look for two managed care teleconferences in January. The first, "Bankruptcy: HMOs, Risk-Bearing Contractors and Providers," will be offered on January 16, 2002 from 1:00 p.m. to 2:30 p.m. Eastern Standard Time. The second, "Managed Care Contracting Handbook," will be offered on January 29-30, 2002 (participants may register for one or both days), and is a follow-up to the handbook published jointly earlier this year by the Hospitals and Health Systems, HMOs and Health Plans and Physicians Organizations Substantive Law Committees. Registration for either teleconference – and orders for the handbook – are being accepted through the AHLA web site, <www.healthlawyers.org>.

In addition, mark your calendars now for the return of the Managed Care Law Institute, to be held May 6-7, 2002 at the Broadmoor Hotel in Colorado Springs, Colorado. Don't forget to sign up for the HMOs and Health Plans SISLC luncheon when you register for the institute.

Finally, please keep in mind that we want all of our members to participate in these and other SISLC education and outreach initiatives. If you are interested in participating in any SISLC activity, or have any suggestions as to how we can better serve you, please do not hesitate to contact any of the SISLC leaders, or AHLA SISLC Coordinator Laurie Garvey at (202) 833-1100.

H M O S & Health Plans Leadership 2001-02

Richard L. Shackelford, Chair

King & Spalding
191 Peachtree Street
Atlanta, GA 30303-1763
Phone: (404) 572-4995
Fax: (404) 572-5142
E-Mail: Rshackelford@kslaw.com

Errol J. King, Vice Chair

McGlinchey Stafford, APLLC
9th Floor
One American Place
Baton Rouge, LA 70825
Phone: (225) 383-9000
Fax: (225) 343-3076
E-Mail: eking@mcglinchey.com

Margit Nahra, Vice Chair and Editor

Crowell & Moring, LLP
1001 Pennsylvania Ave, NW
Washington, D.C. 20004
Phone: (202) 624-2965
Fax: (202) 628-5116
E-Mail: mnahra@cromor.com

Stuart Silverman, Vice Chair

Office of Inspector General for the Government
of the District of Columbia
PO Box 30378
Bethesda, MD 20824
Phone: (301) 897-4896
E-Mail: sisilverman@aol.com

Medicaid at the Cross-Roads: Medicaid Managed Care Under the Bush Administration

R. Jeffrey Layne, Esquire
Lori-Ann S. Bellan, Esquire
Fulbright & Jaworski LLP
Washington, DC

I. Introduction

In 1997, with the Clinton Administration still in the early stages of its second term, the United States Congress sought to encourage the states to enroll Medicaid beneficiaries in managed care programs. Managed care had proliferated in the private sector and was given considerable credit for bringing private healthcare costs under control. The Balanced Budget Act of 1997 (BBA) sought to capture the perceived efficiencies of managed care for the Medicaid program by allowing states, without first seeking a federal waiver, to enroll Medicaid recipients in managed care programs.¹ Recognizing, however, that it was encouraging the states to turn over the administrative responsibility for the healthcare of Medicaid recipients to private entities, Congress took steps to ensure that it adequately protected those beneficiaries from potential managed care abuses. To this end, Congress included in the BBA "patients' rights" provisions for Medicaid managed care enrollees and charged the Centers for Medicare and Medicaid Services (CMS), then known as the Health Care Financing Administration (HCFA), with implementing by regulation a wide array of protections for such enrollees.

Since then, the Medicaid managed care regulations have become something of a political

football, as first the Clinton Administration and then the Bush Administration attempted to craft Medicaid managed care regulations that reflect their respective priorities and philosophies of governance. The recent publication of the Bush Administration's proposed Medicaid managed care regulations, however, provides a glimpse of where the administration is seeking to take Medicaid managed care at a time when many states' programs struggle to address rising costs, shrinking budgets, and fewer and fewer participating private managed care organizations (MCOs).

II. Background

The Medicaid program was created in 1965 as a joint federal and state program for providing medical assistance to low-income people. The program allows each state, within broad federal requirements, to create its own "state plan" establishing Medicaid eligibility standards, benefits, reimbursement, and administrative structure. The federal government, which approves state plans and monitors state compliance with federal regulations, provides matching funds to the states to cover a substantial portion of the costs of Medicaid coverage. In providing coverage, states traditionally have reimbursed Medicaid providers directly on a fee-for-service basis for their care for Medicaid recipients. In recent years, however, states have increasingly sought to provide medical coverage to Medicaid recipients through contracts with MCOs, which agree to cover the appropriate healthcare needs of enrolled beneficiaries in exchange for fixed (or "capitated") payments per

enrollee. Prior to the enactment of the BBA in 1997, states could enroll Medicaid beneficiaries in mandatory managed care plans only if they sought and received waivers from federal requirements for state plans under either § 1915(b) or § 1115 of the Social Security Act.

The BBA revised the Social Security Act to make it easier for states to mandate the enrollment of certain Medicaid beneficiaries in managed care plans. Among other things, the BBA eliminated the requirement that states first seek a federal waiver before establishing a mandatory Medicaid managed care program. The BBA, however, also established new beneficiary protections for Medicaid managed care enrollees to ensure that their interests are adequately protected once administrative responsibility for their care is turned over to private MCOs.

On September 29, 1998, the Clinton Administration proposed new rules for implementing the Medicaid managed care provisions of the BBA.² According to CMS, the 1998 proposed rule received over 300 comments addressing virtually every aspect of its provisions.³ The Clinton Administration did not issue a final rule until January 19, 2001 (the day before President Bush's inauguration), when a final Medicaid managed care rule was promulgated in a flurry of last minute regulatory activity by the outgoing administration.⁴

Shortly after taking office, however, President Bush ordered a sixty-day delay in the implementation of all final rules issued by the Clinton Administration, including the Medicaid managed care rule.⁵ During this delay,

CMS sought further input from key stakeholders, including beneficiaries and their advocates, the states, and health plans. On June 18, 2001, CMS delayed the implementation of the final rule an additional 60 days to August 17, 2001.⁶ When the August 17 implementation deadline arrived, however, CMS once again postponed the deadline for implementing the final Medicaid managed care rules for one year and announced that it would publish another proposed rule on August 20, 2001, which would substantially revise the existing final rule and allow for further comment by the public.⁷

During the course of these delays, Congressional Democrats protested at almost every turn. In a March 29, 2001, letter to Tommy Thompson, the new Secretary of the United States Department of Health and Human Services (DHHS), Congressional Democrats complained that the delay in implementation of Medicaid managed care regulations was "unwarranted" and jeopardized "the ability of low-income children, pregnant women, and people with disabilities to get quality healthcare under the Medicaid program." The Democrats reminded Secretary Thompson that Congress had sought to strike an appropriate balance through the BBA by coupling new flexibility for states with increased protections for Medicaid beneficiaries.

Similarly, on August 13, 2001, with the prospect of further delay looming, the ranking Democrats on the House Energy and Commerce Committee wrote to President Bush to express their frustration with his

Continued on page 10

Continued from page 9

administration's failure to implement the Medicaid managed care rules. The Democrats once again reminded the President and his administration that the BBA represented a trade-off: the federal government would afford states more flexibility in mandating managed care for Medicaid beneficiaries, but in exchange would require states to adhere to federal standards for patients' rights. The ranking Democrats further asserted that the rights set out in the January 2001 final rules were consistent with the patients rights principles already embraced by President Bush with regard to private managed care plans during the political debate over the so-called "Patients' Bill of Rights" legislation.

III. The Bush Administration's Proposed Rules

On August 20, 2001, the Bush Administration issued a Notice of Proposed Rule Making (NPRM)⁸ which would replace the Clinton Administration's previously published final Medicaid managed care regulations.⁹ CMS received comments on the proposed rule through October 19, 2001, and is reportedly looking to publish a new final rule well before its published deadline of August 16, 2002. According to CMS, the proposed rule, among other things, would implement the key components of the BBA by allowing states greater flexibility to amend their state plans to require certain categories of Medicaid beneficiaries to enroll in managed care entities without obtaining waivers; establishing new beneficiary protections in areas such as quality assurance, grievance rights, and

coverage of emergency services; and eliminating certain requirements viewed by state agencies as impediments to the growth of managed care programs, such as the enrollment composition requirement, the right to disenroll without cause at any time, and the prohibition against enrollee cost-sharing.¹⁰

The NPRM, however, differs in several important ways from the Clinton Administration's final rule. The significant differences reflect the different priorities and philosophies of the two administrations. In implementing the requirements of the BBA, the Bush Administration's NPRM leaves many key matters to the discretion of the individual states. This marks a stark contrast to the Clinton Administration's final rules, which would have imposed broader federal requirements and oversight on the states to ensure a more uniform implementation of federal priorities. These key philosophical differences can be seen in, among other things, regulations regarding (1) the specific protections for children and adults with special healthcare needs; (2) performance standards applicable to populations facing an elevated risk of medical underservice; and (3) consumer protections and anti-discrimination provisions.¹¹ The following discussion illuminates several of these differences, but is not intended to be an exhaustive discussion of the differences between the two rules.

A. *Special Healthcare Needs*

The January 2001 rule issued by the Clinton Administration provided increased federal protections for Medicaid beneficiaries with "special healthcare needs."

The Clinton regulations specifically defined this category of beneficiaries to include some of the Medicaid program's most vulnerable populations, including children and adults receiving SSI benefits, children in Title IV-E foster care, beneficiaries 65 or older, and other specified beneficiaries established by CMS and the states.¹² The January 2001 rule also required states and plans to identify enrollees with special healthcare needs and to assess the quality and appropriateness of their care within specific time deadlines.¹³ The Clinton Administration's regulations also required states to establish a mechanism to ensure continued access to care for beneficiaries with ongoing healthcare needs who are transferred from fee-for-service to a managed care health plan, from one health plan to another, or from a health plan to fee-for-service.¹⁴

The Bush Administration's NPRM modifies these requirements in significant ways. For example, the NPRM eliminates the federal continuity of care requirements. In addition, the NPRM eliminates the provision in the January 2001 rule that required health plans to make "best efforts" to provide medical screening to enrollees at risk of having special healthcare needs within thirty (30) days of identification and to all other enrollees within ninety (90) days.¹⁵ The NPRM retains the requirement that states appropriately identify special needs members at the time of enrollment,¹⁶ but provides states with full discretion in defining special needs populations.¹⁷

B. *Underserved Populations*

The January 2001 rule proposed by the Clinton Administration

also mandated specific protections for certain persons at risk of medical underservice, such as migrant and seasonal farm workers and the homeless. The Bush Administration's NPRM, however, proposes to revise or eliminate certain of these protections.¹⁸ For example, the NPRM does not mandate special disenrollment protections for migrant and seasonal farm workers and homeless beneficiaries (e.g., protection from disenrollment when the beneficiary leaves the service area).¹⁹ In addition, the Bush Administration has left the method of implementation of cultural competency requirements to the states' discretion.²⁰ In the end, the proposals relax or remove federal performance requirements regarding the protections for certain persons who are at risk of being medically underserved and leaves such matters more to the discretion of the individual states.

C. *Grievance and Appeal Issues*

The Clinton Administration's regulations required that the states implement a vast array of grievance and appeal protections and processes for Medicaid managed care enrollees. The Bush Administration's NPRM, however, eliminates a substantial number of these federal mandates. For example, the NPRM eliminates the January 2001 rule's requirement that states provide an external review of delays by MCOs in providing care to Medicaid enrollees. The Bush Administration also rejected the Clinton Administration's rule requiring MCOs to automatically forward adverse or delayed appeal decisions to their respective state's fair hearing offices for

external review, as is currently required under the Medicare program.²¹ The Bush Administration also rejected the automatic continuation of benefits that would have occurred with the forwarding of the request for appeal.²² CMS has taken the position that these requirements would be administratively burdensome for the states.²³

D. Other Protections

The Bush Administration's NPRM differs from the January 2001 final rule in several other notable ways. For instance, the Clinton Administration's final rule would have extended enrollee safeguards to all prepaid health plans. The August 2001 NPRM, however, splits prepaid health plans into two categories: prepaid ambulatory health plans (PAHPs) and prepaid inpatient health plans (PIHPs). The NPRM exempts PAHPs from most of the enrollee safeguard requirements. The NPRM also eliminates a considerable number of federal requirements regarding the information that states must require MCOs to provide to Medicaid beneficiaries and specific quality assessment and performance improvement requirements targeted at enrollees with special health-care needs.²⁴ The NPRM also eliminates certain prohibitions designed to prevent discrimination against beneficiaries. This federal safeguard was implemented to ensure that health plans' networks are open to all Medicaid beneficiaries to ensure equal access to health-care services. Again, under the Bush Administration's rules, these issues and others would be left largely to the discretion of the individual states.

IV. Immediate Challenges

The differences between the Bush and Clinton approaches to Medicaid managed care closely mirror the differences between the overall governing philosophies of the two administrations. The Clinton rule would have concentrated control of the Medicaid managed care program with the federal government, which would direct and closely monitor the states' implementation of the BBA's Medicaid managed care provisions. This approach would have allowed the federal government to provide uniform protections for Medicaid beneficiaries across the country and, presumably, to prevent abuses by states less committed to the concept of "patient rights" in general. Arguably, it also would have discouraged states facing spending overruns and budget deficits from cutting corners to the detriment of the rights of Medicaid beneficiaries.

The Bush Administration's NPRM reflects the President's preferences for decentralized authority and state autonomy. Befitting an administration dominated by Republican ex-governors (including President Bush and Secretary Thompson), the NPRM leaves it to the states to determine the details of implementing the BBA's Medicaid managed care beneficiary protections. This approach presumably would allow each state to custom fit such protections to its own circumstances and the needs of its own Medicaid population. The Bush philosophy, recognizing that each state faces its own set of challenges (e.g., the Medicaid program confronts very different problems in Wyoming than in

Massachusetts), arguably would afford each state the opportunity to develop solutions that meet those challenges.

The question of which of the two philosophies would better protect Medicaid managed care enrollees in the current political and economic climate is largely an academic exercise: after the notice and comment period, some version of the Bush NPRM will be implemented, and the Clinton final rule will follow its sponsoring administration into the sunset. Almost assuredly, however, the Bush approach will be put to the test by two factors which have begun to strain state Medicaid programs across the country: (1) increasing growth in Medicaid expenditures and (2) shrinking state revenues.

The current rise in Medicaid expenditures follows a period of restrained growth. From 1995 to 1997, Medicaid spending grew at an average rate of approximately 3.2%, the lowest rate in the history of the program. In 1997, however, the growth rate began to rise again. By 2001, Medicaid expenditures were growing at nearly a 10% clip. This surge in growth is attributed to a number of factors, including (but not limited to): (1) healthcare price inflation in general; (2) substantially increased spending for prescription drugs; (3) an increase in Medicaid enrollment; and (4) a net decrease in the number of managed care plans willing to participate in the Medicaid program, which allows plans remaining in the program to exploit increased market power to secure significant payment rate increases.²⁵

At the same time that Medicaid spending rates have begun to

grow more rapidly, state budgets have begun to shrink. Even before the terrorist attacks of September 11, 2001, many states reported declining tax revenues as a result of the general decline in the economy. The events of September 11 appear to have exacerbated these problems. The economy has declined at an even sharper rate, and state tax revenues have declined precipitously. As a result, many states are facing severe budget pressures and the prospect of dipping into their year-end balances to fund Medicaid budgetary shortfalls. At the same time, the sharp rise in unemployment after the terrorist attacks has increased the demand for public assistance, including Medicaid coverage.²⁶ This combination of an unexpected spike in demand and precipitous drop in state revenues is particularly problematic, because the states simply could not have anticipated it and were unable to budget for it or around it.

In the current atmosphere, most states will face significant challenges in meeting the needs of their Medicaid beneficiaries within the predicted budgetary constraints without increasing appropriations, cutting benefits, and/or finding new efficiencies. It remains an open question whether the Bush Administration's approach to regulating Medicaid managed care will be of benefit to states and their Medicaid beneficiaries or will work to deprive vulnerable Medicaid managed care enrollees of protections from abuses as states struggle to meet their obligations as cost effectively as possible. On the one

Continued on page 12

Continued from page 11

hand, the states may well benefit from having fewer federal regulatory requirements dictating their efforts to craft an effective and efficient Medicaid managed care program. For instance, the states would undoubtedly benefit from retaining existing Medicaid MCOs and attracting more MCOs to their programs, thereby introducing greater price competition and efficiencies. To this end, the states may benefit from increased flexibility in making the program more attractive to MCOs by alleviating or avoiding administrative burdens that would have been mandated by the Clinton rules. The states may also be better served by redirecting resources away from burdensome administrative requirements and towards meeting the fundamental healthcare needs of their burgeoning Medicaid roles.

On the other hand, in the absence of strong federal control over the Medicaid managed care program, states facing growing budgetary crises may be tempted to solve their problems at the expense of their Medicaid beneficiaries, a vulnerable and relatively powerless interest group. In the current economic environment, and in the absence of federal mandates, even states with the noblest of intentions may find it difficult to find the resources to effectively monitor MCOs to assure that the rights and interests of Medicaid beneficiaries are adequately protected.

V. Conclusion

Through the BBA, Congress made it easier for states to enroll

Medicaid beneficiaries in mandatory managed care programs. In exchange, however, Congress included several significant patients' rights provisions in the BBA and charged CMS with developing a regulatory scheme to protect Medicaid beneficiaries from regulatory abuses. The Bush Administration, through the publication of the August 20, 2001 NPRM, has met the Congressional mandate in a way that reflects its own decentralized, state-oriented philosophy of governance. Can the states be trusted to adequately protect the rights of Medicaid beneficiaries in light of the current economic pressures to cut corners? Will the flexibility provided by the NPRM be beneficial to states' efforts to ensure the viability of Medicaid managed care programs? The answers to these questions may become clearer in the months ahead. In the meantime, the states will be challenged to use their newfound responsibilities wisely as they struggle to provide Medicaid coverage (managed care or otherwise) to a growing number of beneficiaries.

Endnotes

- ¹ The BBA also sought to reinvigorate the Medicare managed care program by creating the Medicare + Choice program (Medicare Part C).
- ² 63 Fed. Reg. 52022 (Sept. 28, 1998).
- ³ See 66 Fed. Reg. 43614, 43615 (Aug. 20, 2001).
- ⁴ 66 Fed. Reg. 6228 (Jan. 19, 2001).
- ⁵ 66 Fed. Reg. 11546 (February 26, 2001).
- ⁶ 66 Fed. Reg. 32766 (June 18, 2001).

- ⁷ 66 Fed. Reg. 43090 (Aug. 17, 2001).
- ⁸ 66 Fed. Reg. at 43613.
- ⁹ 66 Fed. Reg. at 6228.
- ¹⁰ 66 Fed. Reg. at 43614.
- ¹¹ *Id.*
- ¹² 66 Fed. Reg. at 6228.
- ¹³ *Id.* See also U.S. Department of Health and Human Services, *New Patient Protections Included in Medicaid Managed Care Rule*, Jan. 18, 2001.
- ¹⁴ U.S. Department of Health and Human Services, *New Patient Protections Included in Medicaid Managed Care Rule*, Jan. 18, 2001.
- ¹⁵ 66 Fed. Reg. at 43635.
- ¹⁶ *Id.*
- ¹⁷ *An Analysis of the Bush Administration's Proposed Medicaid Managed Care Regulations*, The George Washington University Medical Center, Center for Health Services Research and Policy, Sara Rosenbaum, J.D. et al., Sept. 2001.
- ¹⁸ 66 Fed. Reg. at 43628.
- ¹⁹ *Id.* at 43628, 43665.
- ²⁰ *An Analysis of the Bush Administration's Proposed Medicaid Managed Care Regulations*, The George Washington University Medical Center, Center for Health Services Research and Policy, Sara Rosenbaum, J.D. et al., Sept. 2001.
- ²¹ 66 Fed. Reg. at 43640.
- ²² *Id.*
- ²³ *Id.*

- ²⁴ *Pieces of the Puzzle, Implementing the Report to Congress on Safeguards for People with Special Healthcare Needs in Medicaid Managed Care*, The Henry J. Kaiser Family Foundation, Jeffrey S. Crowley, M.P.H., and Stephanie Lewis, M.H.S.A., J.D.
- ²⁵ *Medicaid Budgets Under Stress: Survey Findings for State Fiscal Year 2000, 2001 and 2002*, The Henry J. Kaiser Family Foundation, Vernon Smith, Ph.D. and Eileen Ellis (October 2001).
- ²⁶ *Id.*

Teleconferences

Bankruptcy: HMOs, Risk-Bearing Contractors and Providers - January 16, 2002

Co-sponsored by Healthcare Liability and Litigation, HMOs and Health Plans, and Physician Organizations

Michael Schaff, Esq., Wilentz Goldman & Spitzer PA, Woodbridge, NJ
Alan Bloom, Esq., General Counsel & Senior VP, Maxicare Health Plans, Los Angeles, CA
Kevin Brady, Deputy Commissioner, HMO Division Texas Dept. of Insurance, Austin, TX
James Doherty, Jr., Esq., Pecore & Doherty, LLC, Columbia, MD
Deborah Williamson, Esq., Cox & Smith, San Antonio, TX

Managed Care Contracting Payor - January 29, 2002 Providers - January 30, 2002

Co-sponsored by Hospitals and Health Systems, HMOs and Health Plans, and Physician Organizations

Cynthia Reeves, Esq., Honigman Miller Schwartz & Cohn LLP, Detroit, MI
George Bodenger, Esq., Duane Morris & Heckscher LLP, Philadelphia, PA
Sharon King Donahue, Esq., National Commission on Quality Assurance, Washington, DC
Brian Gradle, Esq., Epstein Becker & Green PC, Washington, DC
J. Peter Rich, Esq., McDermott Will & Emery, Los Angeles, CA
John Kirsner, Esq., Squire Sanders & Dempsey LLP, Columbus, OH
Thomas O'Donnell, Esq., Polsinelli Shalton & Welte PC, Kansas City, MS
Michael Schaff, Esq., Wilentz Goldman & Spitzer PA, Woodbridge, NJ

To Register:

1. Go online to healthlawyers.org/teleconferences.cfm
2. Call 202/833-0766

H M O S Liaison 2001-02

Elizabeth B. Carder, Esquire
Reed Smith, LLP
1301 K Street NW
Suite 1100 E Tower
Washington, DC 20005-3317
Phone: (202) 414-9200
E-Mail: ebcarder@rsm.com

The Debate on a Possible Switch from Prescription to Over-the-Counter Status for Second-Generation Antihistamines

Karen Weiss

3rd year Law Student, George Washington University Law School
Washington, DC

Health Insurers say yes; drug manufacturers say no; consumer groups are mixed. The debate on whether three prescription antihistamines, Claritin (loratadine), Allegra (fexofenadine), and Zyrtec (cetirizine), should switch to over-the-counter (OTC) status is a heated one, and the twists and turns of its history have been interesting and complex. While the debaters have supported their positions with arguments for health and safety, few would deny that economics has been a key concern on all sides.

Antihistamines are medications used to treat allergic rhinitis and related conditions. Older antihistamines such as Clor-Trimeton and Benadryl, have been available OTC for many years. These OTC antihistamines, however, are associated with adverse side effects, the most commonly discussed being sedation. During the past decade, drug manufacturers have developed newer antihistamines, with the purpose of eliminating this effect. These second-generation antihistamines, Claritin, Zyrtec, and Allegra, were approved for marketing in 1993, 1995, and 1996, respectively. Although first-generation antihistamines remain available OTC, the newer generation was limited to prescription-only status pending the development of an enhanced safety record. Ironically, "[t]his regulatory pathway has led to a situation in which the antihistamines that are most associated with sedation are widely available OTC, while the antihistamines that are less likely to be associated with sedation are available by prescription only."¹

In June 1998, WellPoint Health Networks Inc. (formerly Blue Cross of California) filed a Citizen Petition,² asking the Food and Drug Administration (FDA) to switch the three second-generation antihistamines to OTC. On May 11, 2001, the Nonprescription Drug Advisory Committee (NDA) recommended that the FDA approve the switch. Although the FDA asserted its legal authority to demand an OTC switch, it has not yet made a final decision. Typically, the FDA adheres to the advice of the NDA, however the recommendations are not binding.

I. How Does the FDA Decide Whether to Make an OTC Switch?

Every United States citizen has the right to petition the FDA to review the status of a drug and request an OTC switch.³ The FDA may only approve an OTC switch if it determines that adequate labeling allows consumers to use the drug safely and effectively, without the assistance of a medical professional.⁴ If the likelihood that the drugs will provide a "clinically significant benefit of the type claimed in labeling" outweighs the "incidence of adverse reactions or significant side effects under adequate direction for use . . . as well as [the] potential for harm related to any abuse that may occur under conditions of widespread availability," the FDA is likely to approve the OTC switch.⁵

II. Can the FDA Legally Force Drug Manufacturers to Make the OTC Switch?

Drug manufacturers insist that the FDA does not have the legal authority to force them to switch to OTC. Zyrtec's manufacturer, Pfizer, submitted a legal brief in which it noted that before making the decision that a drug is safe and effective for OTC, the FDA must conduct a hearing, requiring the disclosure of confidential information related to the drug manufacturer. Such a disclosure, Pfizer argues, would violate federal laws involving industrial property theft, as well as the manufacturers' constitutional rights.⁶

On June 13, 2001, the FDA "unequivocally" asserted its authority to order an OTC switch, despite the manufacturer's lack of consent.⁷ The FDA is unlikely, however, to make a final decision on whether to approve the WellPoint petition until President Bush appoints a new FDA commissioner. In the event that the FDA requires the OTC switch, manufacturing companies are almost certain to initiate an immediate legal challenge.

III. Deadly Side Effects and Life Threatening Disease: Do Health and Safety Concerns Support or Weaken the Argument for an OTC Switch?

WellPoint argues that "second-generation antihistamines are less toxic and equally efficacious as the first-generation antihistamines."⁸ Studies show that sedation caused by first-generation antihistamines has dangerous consequences. One newspaper reports that there are an estimated 600 deaths and 47,000 injuries each year in the United States as a result of people operating motor vehicles while under the influence of sedating antihistamines.⁹ Similarly, studies show that the effects of first-generation antihistamines on motor vehicle operation are worse than those of alcohol: "[A] single dose of Benadryl is equivalent to a blood-alcohol content of 0.09 – higher than the 0.08 level that makes a driver legally drunk in many states."¹⁰ Second-generation antihistamines, on the other hand, have been "medicinally engineered to stay out of the brain. As a result, they cause little or no sedation."¹¹ Thus, while the Federal Aviation Administration bans pilots from flying while taking OTC antihistamines, it permits pilots to take Claritin and Allegra.

WellPoint conducted a meta-analysis of existing studies, revealing surprising statistics: "Of the 3.5 billion health problems treated annually, almost 2 billion (or 57%) are treated with OTC drugs . . . Americans are 4 times as likely to purchase an OTC medication as they are to consult a physician . . . [and] [a]lmost 60% of all dosage units consumed by patients are for OTC medications."¹² Thus, the prescription status of second-generation antihistamines leaves many patients vulnerable to the dangerous side effects associated with first-generation OTC drugs.

Continued on page 14

Continued from page 13

Manufacturers counter that additional studies are necessary to assess the dangers of second-generation antihistamines in an OTC setting. Schering Plough, for example, claims that WellPoint's meta-analysis does not address several important issues, including the consumer's ability to accurately self-diagnose and comprehend labels, and the risks of misdiagnosis and incorrect dosing.¹³ Manufacturers and doctors argue that absent medical supervision, consumers are likely to overlook and mask serious and potentially life threatening illnesses, including asthma. Moreover, manufacturers insist that patients who currently pay minimal co-payments for second-generation antihistamines under their insurance plans will be forced to switch to less safe first-generation OTC drugs.¹⁴

Nevertheless, manufacturers have not produced any data indicating that confusion of asthma for allergy symptoms has caused widespread problems for current OTC antihistamine users.¹⁵ Moreover, even if consumers do not understand all of the pros and cons of the various antihistamines, pharmacists can play a primary role in assisting consumers in making choices and providing needed advice.¹⁶ Second-generation antihistamines have already been approved for OTC in other countries, including Canada, Germany, and Britain. Notably, an official at Schering-Plough is reported as admitting that in Canada there have been less than 100 reports of adverse incidents involving these OTC drugs.¹⁷

IV. What are the Economic Considerations of an OTC Switch?

While the FDA bases its decision for an OTC switch on safety, effectiveness, and the ability of the consumer to self-diagnose, manufacturers, consumers, and insurers all consider cost to be an important factor, if not the most compelling consideration.

Since the FDA approved second-generation antihistamines for marketing, drug manufacturers have heavily promoted Zyrtec, Allegra, and Claritin through much criticized direct-to-consumer (DTC) advertising. In 1999 alone, drug manufacturer Schering-Plough spent a total of \$185.1 million to advertise Claritin.¹⁸ Ironically, at the same time that Schering-Plough and Aventis Web appear on national television touting their drugs as no more dangerous than sugar pills and placebos, they argue to the FDA that the same drugs have not been proven sufficiently safe for an OTC switch. DTC advertising is intended to encourage consumers to solicit second-generation antihistamines from their doctors, and physicians are reportedly willing to prescribe a particular drug about 80% of the time that a patient specifically asks for it.¹⁹ A switch to OTC status, however, could have a significant detrimental impact upon manufacturers. Although millions of consumers are expected to switch to second-generation antihistamines in the event of an OTC switch, manufacturers will likely lose more money than they will gain, due to the expected 50% price drop once their drugs hit the competitive market.²⁰ In addition, financial analysts predict that an OTC switch will result in significant drops in the price of stock,

which could leave already-struggling manufacturer Schering-Plough vulnerable to a potential takeover.²¹ Furthermore, given increased sales and the removal of a doctor's supervision, drug manufacturers may also face increased product liability risks.²²

Insurance companies, on the other hand, stand to gain immensely from an OTC switch. WellPoint spends between \$30 million and \$50 million per year to cover allergy medications for its insured. According to WellPoint CEO Leonard Schaffer, OTC status would save WellPoint "\$90 million in drug costs and 'unnecessary' doctor visits."²³

The effects on consumers is less clear. Manufacturers argue that currently-insured patients will either lose money or be forced to switch to less expensive, more dangerous antihistamines in the event of an OTC switch. One commentator argues: "If the FDA converts the three products . . . to OTC status, millions of Americans will be shouldering the billions of dollars in costs to buy the drugs, while insurance companies save big."²⁴ Nevertheless, WellPoint Vice President Robert Seidman retorts, it "is not only about my 10 million members who have prescription drug coverage," but it is also for "the 40 million Americans who have no drug coverage and who are spending \$85 a month out of pocket."²⁵ Many people, especially low income Americans and senior citizens, rely on first-generation antihistamines because they are uninsured and unable to afford doctor visits and the exorbitant costs of prescription antihistamines. Thus, WellPoint argues that the prescription status of second-generation antihistamines "deprives a majority of patients ready access to quality pharmaceutical care. This lack of access results in a greater incidence of side effects associated with the OTC alternatives adding considerable unnecessary medical costs to the health-care system."²⁶

Further, an OTC switch would arguably benefit even the uninsured in the long run. If second-generation antihistamines are switched to OTC, competition is likely to force prices down by 50%. In Canada, for example, OTC status makes Claritin available for only \$.70 before taxes.²⁷ Further, one commentator points out that, "[a]lthough consumers with prescription plans pay little or nothing for Claritin, Allegra and Zyrtec at the point of sale, the cost of these medications shows up in higher insurance rates."²⁸ Thus, insured individuals may ultimately experience savings from OTC status in lower premiums.

V. Whether the Issue is Economics or Deadly Side Effects and Life Threatening Disease, an OTC Switch May Make Sense

USA Today reports that U.S. consumers and insurers pay \$1.3 billion a year for Claritin and another \$1.3 billion in doctors visits for prescriptions.²⁹ If the FDA determines that second-generation antihistamines are sufficiently safe and effective for OTC status, and, in fact, even less dangerous than current OTC first-generation alternatives, then maintaining them at prescription status makes the American healthcare system grossly inefficient. Pending the installation of a Bush-appointed FDA commissioner, the likelihood that the FDA

will make that determination remains uncertain. Unfortunately, experts do not anticipate a resolution any time soon.³⁰ In the meantime, anxious insurers, drug manufacturers, and consumers will continue their debate.

Endnotes

¹ FDA Nonprescription Drug Advisory Committee (NDA), Executive Summary on Risk Issues (Draft), available at <www.fda.gov/ohrms/dockets/ac/01/briefing/3737b_03_risk.html>.

² 21 C.F.R. § 10.30 (2001)

³ 21 C.F.R. § 10.30 (2001).

⁴ Durham-Humphrey Amendment to Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 353 (2001).

⁵ FDA Ctr. for Drug Evaluation & Research (CDER), Questions and Answers: Over-the-Counter Drug Products Public Hearing (June 2001), available at <www.fda.gov/cder/meeting/otcqa-600.htm>.

⁶ Milt Freudenheim, *Panel Says 3 Allergy Drugs Should be Sold Over the Counter*, THE NEW YORK TIMES, May 12, 2001.

⁷ *FDA Asserts Authority Over Allergy Prescriptions*, NATIONAL JOURNAL'S CONGRESS DAILY, June 13, 2001.

⁸ Petition by Blue Cross of California (now WellPoint Health Networks Inc.) to the FDA, July 21, 1998.

⁹ Sandra Levy, *Many R.Ph.s support switching antihistamines from Rx to OTC*, DRUG TOPICS, June 4, 2001.

¹⁰ *Access/Quality/Cost Allergy Drugs: Rx Drugs Safer than OTC Medications*, AMERICAN HEALTH LINE, Apr. 12, 2000.

¹¹ Stephen S. Hall, *The Claritin Effect; Prescription for Profit*, THE NEW YORK TIMES, Mar. 11, 2001.

¹² Petition by Blue Cross of California (now WellPoint Health Networks Inc.) to the FDA, July 21, 1998.

¹³ Schering-Plough Research Inst., Briefing Book (April 2001).

¹⁴ Karen Kaplan, *Consumers May Lose Insurance Coverage for Allergy Medications*, THE DAY, June 10, 2001.

¹⁵ Freudenheim, note 6 *supra*.

¹⁶ Levy, note 9 *supra*.

¹⁷ Aaron Schacter, *Why Some Allergy Medicines that are now Prescription Medications Should be Over-the-Counter Drugs*, MARKETPLACE MORNING REPORT, May 24, 2001.

¹⁸ Scott Hensley, *Prescription Costs Become Harder to Swallow: Providers and Payers Get a Big Dose of Reality with Explosive Spending and Patient Demand for New Drugs*, MODERN HEALTHCARE Aug. 23, 1999.

¹⁹ *FDA grappling with allergy decision that would make your eyes water*, GANNETT NEWS SERVICE, June 6, 2001.

²⁰ Merrill Matthews, *WellPoint vs. Big Pharma*, NATIONAL REVIEW, May 17, 2001.

²¹ Freudenheim, note 6 *supra*.

²² Matthews, note 20 *supra*.

²³ *Politics and Policy WellPoint: Post Looks at OTC Campaign*, AMERICAN HEALTH LINE, May 10, 2001.

²⁴ Kaplan, note 14 *supra*.

²⁵ *Over-the-Counter Switch for Allergy Drugs Could Ease Health Plans' Rx Budgets*, MANAGED CARE WEEK, Apr. 2, 2001.

²⁶ Petition by Blue Cross of California (now WellPoint Health Networks Inc.) to the FDA, July 21, 1998.

²⁷ Peterson, *A Push to Sell Top Allergy Drugs Over the Counter*, THE NEW YORK TIMES, May 11, 2001.

²⁸ Jacob Sullum, Commentary, *Paying Through the Nose*, WASHINGTON TIMES, May 23, 2001.

²⁹ *Access/Quality/Cost Allergy Drugs: Rx Drugs Safer than OTC Medications*, AMERICAN HEALTH LINE, Apr. 12, 2000.

³⁰ John Hanchette, *FDA Grappling with Allergy Decision that Would Make Your Eyes Water*, GANNETT NEWS SERVICE, June 6, 2001.

Health Lawyers' Publications

MANAGED CARE CONTRACTING HANDBOOK: A GUIDE FOR PAYORS AND PROVIDERS, 4th EDITION*

by the Managed Care Contracting Handbook Task Force of the Hospitals and Health Systems and HMOs and Health Plans Substantive Law Committees
Cynthia F. Reaves, Esquire, Editor

Robert M. Keenan III, Esquire, Co-Editor

© 2001, - 260 pages, softbound, Practice Guide

(includes CD-ROM)

Item WAA200101

Members \$95 / Non-Members \$110

HEALTHCARE COMPLIANCE LEGAL ISSUES MANUAL, 2ND EDITION

(previously titled "Healthcare Model Compliance Manual")

by the Corporate Compliance Task Force of the In-House Counsel Special Interest Committee of the American Health Lawyers Association.

Task Force Chairs: Robert W. Biddle, Esq., Ankur J. Goel, Esq., and Karen Duke Schuller, Esq.

If you are outside or in-house counsel for hospitals or other healthcare providers, then you'll need this volume to make sure your employer or client has all of their compliance bases covered.

© 2001 3-ring binder, Practice Guide

Item WAA200102

Members \$135 / Non-Members \$160

U.S. HEALTH LAW AND POLICY 2001: A GUIDE TO THE CURRENT LITERATURE

by Donald Caldwell, Jr, Esq.

© 2001, 624 pages, hardbound

Desktop Reference

Item WB200101

Members \$105 / Non-Members \$120

To order, go online to www.healthlawyers.org/ecommerce

Recent OIG Advisory Opinions Address Health Plan Arrangements

Robert N. Rabecs, Esquire
Hogan & Hartson LLP
Washington, DC

The Department of Health and Human Services (DHHS) Office of Inspector General (OIG) issued two advisory opinions earlier this year that are relevant to health plans. The advisory opinions address the permissibility under the Federal Healthcare Programs Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, of certain financial relationships that health plans have with contracting healthcare providers and enrollees. In Advisory Opinion 01-13, the OIG concluded that a provider's agreement to waive Medicare coinsurance charges in a network of health maintenance organizations and skilled nursing facilities could potentially violate the Anti-Kickback Statute. Similarly, in Advisory Opinion 01-15, the OIG concluded that a proposal by Medicare+Choice (M+C) plans to subsidize the premiums and copayments of enrollees who are eligible for both Medicare benefits and limited Medicaid benefits could also potentially violate the Anti-Kickback Statute. In both cases, however, the OIG chose not to impose administrative sanctions on the parties.

I. Advisory Opinion Process

The OIG opinions were issued pursuant to the OIG's advisory opinion process. For years, healthcare providers and their counsel have struggled with the interpretation of vague and complex federal healthcare fraud and abuse laws. Recognizing the lack of clarity in these statutes, as part of the Health Insurance Portability and Accountability Act of 1996 (HIPAA), Congress directed the "Secretary [of Health and Human Services], in consultation with the Attorney General," to issue advisory opinions, upon request by the regulated community, regarding the application of certain statutes to specific proposed transactions.¹ Under HIPAA and its implementing rules, parties to a transaction can request advisory opinions addressing the following questions: (1) What constitutes "prohibited remuneration" under the Anti-Kickback Statute; (2) Whether an actual or proposed arrangement satisfies the criteria for an exception to the Anti-Kickback Statute prohibitions; (3) Whether an actual or proposed arrangement meets the criteria of a regulatory "safe harbor"; and (4) Whether a specified actual or proposed activity constitutes grounds for the imposition of sanctions under the Anti-Kickback Statute, civil money penalty law, or exclusion statutes. The OIG will not address the fair market value of goods, services, or property, or whether an individual is a bona fide employee. Advisory opinions are binding only on the government and on the party seeking the opinion. A party's failure to seek an opinion may not be introduced into evidence to show that the party intended to violate the healthcare fraud and abuse statutes. Since the inception of the process, the OIG has issued a number of opinions pursuant to this process. Those opinions can be obtained from the OIG's website at <www.hhs.gov/progorg/oig>.²

II. Anti-Kickback Statute

The Anti-Kickback Statute makes it a criminal offense for anyone to knowingly and willfully offer, pay, solicit, or receive any remuneration to induce or reward referrals of items or services reimbursable by a federal healthcare program (e.g., Medicare or Medicaid). Violation of the statute constitutes a felony punishable by a maximum fine of \$25,000, imprisonment up to five years, or both. Conviction will also lead to automatic exclusion from federal healthcare programs. The OIG may also initiate administrative proceedings to impose civil monetary penalties on such party.³ By its terms, the statute ascribes criminal liability to parties on both sides of an impermissible "kickback" transaction. For purposes of the Anti-Kickback Statute, "remuneration" includes the transfer of anything of value, directly or indirectly, overtly or covertly, in cash or in kind. The statute has been interpreted to cover any arrangement where one purpose of the remuneration was to obtain money for the referral of services or to induce further referrals.⁴

III. Advisory Opinion 01-13

In Advisory Opinion 01-13, released August 24, 2001, the OIG concluded that a provider's agreement to waive Medicare coinsurance charges in a network of health maintenance organizations and skilled nursing facilities could potentially generate prohibited remuneration under the Anti-Kickback Statute. However, the OIG said it would not impose administrative sanctions in connection with the arrangement. The advisory opinion was the second issued by the OIG on the arrangement. In 1998, the OIG ruled that a nursing home's agreement to forgo payment from a health plan or beneficiary if Medicare's payment matches an agreed-upon fee schedule might violate the Anti-Kickback Statute.⁵ In Advisory Opinion 01-13, the OIG said a different requester provided the OIG with information "that was not available" at the time of the earlier opinion.

The health plan requesting the opinion was a nonprofit corporation licensed as an HMO. The plan's primary business was a commercial HMO product, which covered approximately 350,000 enrollees, of whom less than 5% had primary coverage under Medicare. The plan and its affiliated companies offered other healthcare products, including a point-of-service plan, traditional indemnity coverage, M+C and Medicaid managed care plans, and administrative services for self-funded benefit programs. Those products, in the aggregate, covered approximately 70,000 lives. The plan's advisory opinion request related solely to the plan's commercial HMO product.

The plan provided health services to commercial HMO enrollees through a contractual network of more than 4,700 providers, including sixty-three nursing facilities. The coordination of benefits (COB) provision in the plan's participating provider agreements described the coverage formula to be applied when a plan enrollee had two or

more forms of medical coverage and the plan was the secondary payer. Specifically, the COB provision contained in the provider agreements stated that when the plan was secondary, it would only pay when the plan's allowed amount had not been paid to a participating provider by the primary plan. If the plan's allowed amount had been paid to a participating provider by the primary plan, then the provider would hold the plan enrollee harmless for all charges. Thus, the COB provision contained in the nursing homes' provider agreement with the plan (1) released the plan from any obligation to pay benefits where the nursing facility had already received payment from the patient's primary insurer in an amount equal to or exceeding the plan fee schedule amount, and (2) required the nursing facility to hold the plan's enrollees harmless from any charges, including copayments, coinsurance amounts, and deductibles.⁶

In the advisory opinion, the OIG expressed its longstanding concern with arrangements under which healthcare providers routinely waive cost-sharing amounts that are required under Medicare (including agreements between insurers and providers that require providers to waive Medicare cost-sharing obligations as a condition of participation in an insurance company's network).⁷ Specifically, the OIG said that the arrangement could potentially generate prohibited remuneration under the Anti-Kickback Statute if the requisite intent to induce or reward referrals of federal healthcare program business were present. However, the OIG decided not to impose administrative sanctions in connection with the arrangement.

The OIG said its concern regarding the arrangement was lessened for several reasons. First, the financial benefit to the plan would be negligible because the number of enrollees in which Medicare is the primary payer is less than 5% of the plan's total enrollment. In other words, the effect of the COB provision on potential Medicare coinsurance obligations appeared to be relatively infrequent in the context of a commercial plan consisting primarily of non-Medicare enrollees. Second, the potential financial advantage to the plan is also limited given the regulatory requirement of community rating for premiums and state oversight of rates. Thus, coinsurance waivers should not result in substantially increased profits. Furthermore, under the state regulatory scheme, the premium charged by the plan is the same for all purchasers who have the same benefit package. Thus, the plan has little incentive to manipulate the fee schedule to maximize waivers of coinsurance amounts because it will not be in a position to offer lower premiums for the same benefit package to Medicare-heavy groups and populations. Third, the plan's ability to influence patient referrals is limited by the fact that nursing facility placement is governed by the discharging hospital, the facility's geographic proximity to the patient, and the availability of space. Fourth, the arrangement is unlikely to have an adverse impact on Medicare because the nursing facilities will receive the same reimbursement (or potentially more) from Medicare for Medicare beneficiaries as it will receive for the substantially larger number of enrollees for which the plan is primary. Fifth, a nursing facility's inability to collect coinsurance would not increase the like-

lihood that the nursing facility will reduce services to the plan's Medicare enrollees because the nursing facility will not receive less reimbursement for those enrollees.⁸

IV. Advisory Opinion 01-15

In Advisory Opinion 01-15, released September 26, 2001, the OIG concluded that an arrangement proposed by M+C health plans to pay the premiums and copayments for beneficiaries eligible both for Medicare and Medicaid could potentially generate prohibited remuneration under the Anti-Kickback Statute. Specifically, the OIG said the Anti-Kickback Statute could be implicated by the arrangement because it provides a financial benefit that could induce so-called dually-eligible beneficiaries to seek treatment at the M+C plans offering the subsidies. The fact that a beneficiary is already a patient is irrelevant because the payment may influence the patient's future choice of providers. However, the OIG said it would not impose administrative sanctions on the parties.

The plans requesting the opinion were nonprofit managed care organizations that provided prepaid comprehensive medical care to their enrollees. Specifically, the plans were group model plans that delivered healthcare services through affiliated medical groups that contracted with the plans under bilaterally exclusive contracts referred to as Medical Service Agreements (MSAs). The affiliated medical groups provided virtually no medical services other than those provided pursuant to the MSAs. The MSAs provided that the requestors' payments to each medical group would be negotiated annually and that the basic contractual payment be the product of an agreed upon capitation rate and the number of health plan members enrolled in a given month. These payments did not include the plans' copayments for medical services.

Each of the plans contracted with the Centers for Medicare & Medicaid Services (CMS) to offer a M+C product. The plans were responsible, directly or indirectly, for providing all care to enrollees of its M+C products. The plans covered approximately 650,000 M+C members. Of these, approximately 36,000 members (or 5.5%) were entitled to some level of Medicaid benefits as well. These so-called dually-eligible beneficiaries fell into two categories: (1) those Medicare beneficiaries who qualified for full Medicaid benefits; and (2) those Medicare beneficiaries for whom Medicaid provided assistance only with some or all of the beneficiaries' cost-sharing obligations of Medicare coverage. For dually-eligible beneficiaries, CMS paid M+C plans a higher capitation rate to compensate them for the generally higher level of healthcare utilization that these beneficiaries generated.

The plans believed that dually-eligible beneficiaries, who tend to be poorer than other Medicare beneficiaries, are less likely to be able to afford the M+C plans' copayments and premiums and, therefore, are more likely to disenroll from M+C rather than pay the premiums and copayments. The plans also believed that disenrollment would impact negatively on the continuity and quality of the dually-

Continued on page 18

Continued from page 17

eligible beneficiaries' access to medical care. M+C regulations permit a M+C plan to contract with a state Medicaid agency for the latter to pay all or part of the M+C plan premiums and copayments on behalf of dually-eligible beneficiaries. The plans were taking steps to enter into such contracts with state Medicaid agencies. However, to the extent that these efforts were unsuccessful, the plans would seek to pay the M+C plans' premiums and copayments on behalf of the dually-eligible beneficiaries.

The OIG said the Anti-Kickback Statute could be implicated by the arrangement because it provided a financial benefit that could induce dually-eligible beneficiaries to seek treatment at the M+C plans offering the subsidies. However, the OIG decided not to impose administrative sanctions for several reasons. First, the OIG concluded that the insurer and provider are the same entity, so the plan would, in essence, be paying itself or waiving the beneficiary's fee when it subsidized all or a portion of a dually-eligible beneficiary's healthcare costs. In other words, each plan essentially paid itself the beneficiary's plan premiums and copayments. Thus, the OIG considered the payment to be functionally indistinguishable from a waiver of premiums and copayments by the provider. In both cases, the payments are for services that the plan itself provides, and the plan is simply forgoing money that it might otherwise collect from the enrollee. Second, according to the OIG, it is longstanding policy that a provider is free to waive a Medicare beneficiary's cost sharing obligations based on an individualized determination of financial need. In this case, the plans would rely on the applicable Medicaid agencies' determinations of Medicaid eligibility. The monthly determinations of Medicaid eligibility by state Medicaid agencies would serve as a reasonable and reliable substitute for individualized determinations of financial need. In other words, in lieu of making any independent determination of dually-eligible beneficiaries' financial need, the plans would rely on the state Medicaid agencies' determinations of the beneficiaries' Medicaid status. Third, the plans would not advertise the existence of the premium and copayment subsidy, nor promote it in any marketing material. In this regard, the plans would obtain CMS' prior written approval regarding the content and wording of the plans' letters to dually-eligible beneficiaries enrolled with the plans informing them of the premium and copayment subsidy's availability, as well as the terms, conditions, and eligibility requirements.⁹

V. Conclusion

In sum, the OIG advisory opinion process offers health plans an opportunity to obtain some guidance regarding the permissibility of various types of financial arrangements that plans may have with participating providers and plan enrollees. The two advisory opinions recently issued by the OIG have relevance for assessing such arrangements. In these opinions, the OIG indicated that certain types of coinsurance waivers and premium subsidization programs used by health plans may potentially implicate the Anti-Kickback Statute. The decision by the OIG not to impose administrative

sanctions in both cases should not necessarily be taken as evidence that the OIG will approve all such arrangements. The reasons for the OIG's decision not to impose sanctions are highly fact-specific and, therefore, plans should proceed with caution before relying upon these opinions in adopting the practices at issue.

Endnotes

¹ Health Insurance Portability and Accountability Act, § 205, 110 Stat. 2001. See 42 U.S.C. § 1320a-7d(b).

² 42 U.S.C. § 42 U.S.C. 1320a-7d(b)(4); 42 C.F.R. Part 1008; 62 Fed. Reg. 7350 (Feb. 19, 1997).

³ 42 U.S.C. § 1320a-7d(b).

⁴ See, e.g., *United States v. Kats*, 871 F.2d 105 (9th Cir. 1989); *United States v. Greber*, 760 F.2d 68 (3d Cir. 1985), cert. denied, 474 U.S. 988 (1985).

⁵ OIG Advisory Opinion No. 98-5 (Dep't of Health & Human Servs., April 24, 1998).

⁶ The following hypothetical example is illustrative of how the COB provision in question worked. For purposes of this example, the nursing facility's Medicare per diem rate is \$300/day. The Medicare coinsurance is \$95/day for days 21-100. The plan fee schedule rate is \$225/day. One of the plan's Medicare enrollees is admitted to the nursing facility for a 31 day stay. A Medicare coinsurance of \$950 (\$95 x 10 days) applies to the last 10 days. For those days, the nursing facility is entitled to Medicare reimbursement of \$3,000 (\$300 x 10 days). Medicare pays the nursing facility \$2,050 (\$3,000 - \$950 coinsurance). The nursing facility bills the plan for the \$950 coinsurance. The plan, applying its COB provisions, limits the nursing facility's reimbursement to \$2,250 (\$225 x 10 days). The plan pays the nursing facility \$200 (\$2,250 - \$2,050 Medicare payment). The nursing facility still has a balance owing of \$750 for the Medicare coinsurance. Under its agreement with the plan, the nursing facility is prohibited from billing the plan's Medicare enrollee for the balance of the coinsurance. The balance of the Medicare coinsurance owed to the nursing facility is effectively waived.

⁷ See, e.g., Special Fraud Alert, "Routine Waiver of Copayments or Deductibles Under Medicare Part B" (May 1991) reprinted in 59 Fed. Reg. 65,374 (Dec. 19, 1994).

⁸ OIG Advisory Opinion No. 01-13 (Dep't of Health & Human Servs., Aug. 17, 2001).

⁹ OIG Advisory Opinion No. 01-15 (Dep't of Health and Human Servs., Sept. 19, 2001).

Program Registration Form



Managed Care Law Conference
May 5-7, 2002

The Broadmoor - Colorado Springs, Colorado

Cancellations/Substitutions:

Cancellations must be received in writing no later than April 24, 2002. Registration fees, less a \$100 administrative fee will be refunded following the program. If you wish to send a substitute, please call the Health Lawyers Member Service Center at 202/833-0766. Please note that registration fees are based on the membership status of the individual who actually attends the program.

Hotel:

Hotel accommodations are not included in the registration fee. Call The Broadmoor Hotel at 800/634-7711. Indicate that you are attending the Health Lawyers program to be eligible for the special group rates. The room block expires April 5, 2002. (Rooms at the group rate are limited and may sell out prior to the cut-off date).

To register: Remit payment and completed registration form

by mail to the American Health Lawyers Association, PO Box 79340, Baltimore, MD 21279-0340

by fax with credit card information to (202) 833-1105 by phone to AHLA Member Service Center at 202/833-0766

To avoid duplicate charges, please do not mail this form if you have already faxed it to us.

Name: _____ AHLA Member ID #: _____

First Name for Badge (if different than above): _____

Title: _____

Organization: _____

Address: _____

City: _____ State: _____ Zip: _____

E-mail: _____

Telephone: (____) _____ Fax: (____) _____

This is a new address; please update my file.

REGISTRATION FEES *(fees increase by \$100 after April 5, 2002):*

AHLA **Members:** \$795

Non-Members: \$995

Special Interest and Substantive Law Committee Mid-Year Meeting

(all registrants are welcome to register for this presentation and networking opportunity)

HMOS and Health Plans (Tuesday, May 7, 2002) \$37

PAYMENT INFORMATION

Total Enclosed: \$ _____

(Sorry! Registrations cannot be processed unless accompanied by payment.)

Check enclosed (U.S. funds; make payable to American Health Lawyers Association)

Bill my credit card: VISA MasterCard American Express

Card Number: _____ Exp. Date: _____

Name of Cardholder: _____

Signature of Cardholder: _____

ZIP Code of Cardholder's Billing Address: _____ - _____

Please note: AHLA will charge your credit card for the correct amount if your total is incorrect.

501(C)(3) FED ID No. 23-7333380 SN

Databanks: They're Not Just for Hospitals Anymore

Alicia Palmer, Esquire
Crowell & Moring LLP
Washington, DC

Earlier this year, the Office of Inspector General (OIG) of the United States Department of Health and Human Services (DHHS) issued a report (the *OIG Report*)¹ that put managed care organizations (MCOs) "under the spotlight" with respect to filing reports with the National Practitioner Data Bank (NPDB) and the Healthcare Integrity Protection Data Bank (HIPDB). This article addresses the general reporting requirements applicable to MCOs with respect to both databanks, as well as practical issues encountered by MCOs attempting to comply with those requirements.

I. The National Practitioner Data Bank

A. What is the NPDB?

The NPDB was established pursuant to the Health Care Quality Improvement Act of 1986 (HCQIA) and is designed to collect information relating to the competency of healthcare professionals. The types of information collected include medical malpractice payments, licensing actions by medical boards based on professional competence or conduct, and formal peer review or clinical privileging actions by healthcare entities.² The information in the NPDB is primarily used by state and federal licensing/certification agencies, hospitals, and other healthcare entities to ensure healthcare practitioners are professionally competent and may appropriately be licensed, contracted with, or hired.

B. Who Must Report to the NPDB?

Under the current statute and regulations, only state Boards of Medical Examiners and entities which make payments arising out of claims of medical malpractice are obligated to report directly to the NPDB.³ However, "health care entities" must report adverse actions on clinical privileges to the applicable state Board of Medical Examiners.

A healthcare entity is defined here to include "an entity that provides health care services, and engages in professional review activity through a formal peer review process for the purpose of furthering quality health care..."⁴ As will be discussed, a small number of MCOs may not qualify as healthcare entities if they do not engage in professional review activity through a formal peer review process.

"Professional review activity" is action taken by an entity to determine if the organization will offer a provider clinical privileges or, if a provider already has privileges, whether the entity should limit or terminate such privileges. A "formal peer review process" occurs when the entity conducts its professional review activity through formally-adopted written procedures, and such procedures give the provider adequate notice and an opportunity for a hearing.⁵

While most, if not all, MCOs engage in some form of professional review activity (e.g., the MCO reviews provider contracts or provider employment applications to determine if the MCO should employ the provider or accept the provider into the MCO's network), some

MCOs may not have a formal peer review process.⁶ Thus, the MCO may not have written procedures for review of provider employment and/or network applications, or the suspension or termination of provider employment or network contracts. Further, the MCO's procedures may not give the provider adequate notice and an opportunity for a hearing. It should be noted that if an MCO is not a healthcare entity as defined in the NPDB regulations, the MCO may not query the NPDB regarding a particular provider.⁷

An additional consideration is that, if an MCO seeks accreditation from the National Committee for Quality Assurance (NCQA) and the MCO does not have a formal peer review process as defined in the NPDB regulations, the MCO may have to adjust its processes to meet the NCQA standards. NCQA takes the position that its credentialing standards define an MCO's "credentialing committee review as a peer review process and it is the intent of NCQA's Credentialing Standards that credentialing follow a formal peer review process."⁸ Thus, NCQA requires MCOs that participate in the NPDB to obtain NPDB information with respect to provider credentialing and recredentialing.⁹ If the MCO does not participate in the NPDB, NCQA requires that the MCO obtain several other items of information to meet the NCQA requirement.¹⁰

On their face, the NPDB regulations require healthcare entities to report adverse action on clinical privileges to the appropriate state Board of Medical Examin-

ers; in turn, the state Board of Medical Examiners is required to forward any reports from healthcare entities to the NPDB. In practice, however, healthcare entities are expected to make reports directly to the NPDB.¹¹ When the NPDB regulations were promulgated, the NPDB reporting system was paper-based. Under that system, a healthcare entity submitted a paper report of an adverse action to the Board of Medical Examiners for the state in which the healthcare entity was located, and that board submitted a report to the NPDB. After the promulgation of those regulations, however, the NPDB moved to an electronic reporting system. As a result of this conversion, the Health Resources and Services Administration (HRSA)¹² expects healthcare entities to file electronic reports directly to the NPDB and to send a paper copy of the report to the appropriate state Board of Medical Examiners.¹³

C. What Must Healthcare Entities Report to the NPDB?

Healthcare entities must report adverse actions on clinical privileges of physicians and dentists.¹⁴ An entity may also report adverse actions taken against other healthcare practitioners, but is not required to do so.¹⁵ Adverse actions on clinical privileges are defined as: (1) any professional review action that adversely affects the clinical privileges, or any restriction of such privileges, for a period of thirty days or more; or (2) a healthcare entity's acceptance of a provider's surrender of clinical privileges while the provider is under investigation by the

healthcare entity for incompetence or improper professional conduct, or in return for not conducting such an investigation.¹⁶

“Clinical privileges” are defined as the authorization a healthcare entity gives to a provider to furnish healthcare services. As applied to MCOs, an adverse action on clinical privileges would be the limitation, suspension, or termination of a provider’s ability to render services to an MCO’s members. MCOs could limit, suspend, or terminate a provider’s clinical privileges either through termination or a restriction of the provider’s employment with the MCO or the provider’s contract.

In addition to affecting clinical privileges for more than thirty days, an adverse action under the NPDB regulations must also be as a result of a professional review action. For a provider employment or contract action to be a professional review action, it must: (1) be taken in the course of professional review activity; (2) be based upon the provider’s professional competence or conduct, and such competence or conduct adversely affects or may affect a patient’s/ member’s health or welfare; and (3) affect the provider’s contract or employment with the healthcare entity. Thus, if an adverse contract or employment action taken by an MCO that qualifies as a healthcare entity against a provider was not taken as a result of the MCO’s formal peer review process, the action is not reportable to the NPDB. Examples of non-reportable actions include employment or contract terminations resulting from another entity’s action (e.g., a

state medical board revokes a dentist’s license), and termination of a provider’s employment or network contract because the provider is submitting fraudulent claims (but see the following discussion of HIPDB). The latter is non-reportable even if the entity that took the action upon which the MCO based its employment or contract termination did so via a formal peer review action. For example, if a hospital terminates a physician’s admitting privileges and the MCO terminates the provider’s contract because of the hospital’s action, the MCO’s contract termination is not reportable to the NPDB.

D. What Happens if a Healthcare Entity Fails to Report a Reportable Action to the NPDB?

If an entity’s peer review committee conducts itself in accordance with the procedures set forth in 42 U.S.C. § 11112, the committee and members of the committee will not be liable for any professional review actions taken by the committee.¹⁷ This liability protection is not available, however, if, after an investigation and opportunity for a hearing, the Secretary of DHHS determines an entity has failed substantially to report information to the NPDB or the appropriate Board of Medical Examiners. If the Secretary makes such a finding, s/he will publish the name of the healthcare entity in the *Federal Register*, and the entity will not have the liability protection of 42 U.S.C. § 11111 for three years, starting thirty days after the date of publication in the *Federal Register*.¹⁸

The OIG Report indicated that MCOs (as well as other healthcare entities) are required to

submit reports directly to the NPDB.¹⁹ However, as indicated, that requirement stems from HRSA’s *NPDB Guidebook* and is not required by the NPDB regulations. The regulations require healthcare entities to report adverse actions taken with respect to clinical privileges to the applicable State Board of Medical Examiners. Absent a revision to the law and or regulations, if a healthcare entity properly reported its actions to the State Board of Medical Examiners rather than the NPDB, the OIG could not take any kind of punitive action against the healthcare entity.

E. Does a Healthcare Entity Have to Query the NPDB?

With the exception of hospitals, a healthcare entity does not have to query the NPDB. However, as discussed, to obtain NCQA accreditation, MCOs registered with the NPDB must query the NPDB as part of the NCQA credentialing and recredentialing criteria.²⁰

II. The Healthcare Integrity Protection Data Bank

A. What is the HIPDB?

The HIPDB is part of a healthcare fraud and abuse control program established by the Health Insurance Portability and Accountability Act of 1996. The database, administered by the HRSA on behalf of the OIG, is intended to house data regarding potential fraud and abuse information about healthcare providers. The following actions must be reported to the HIPDB:

- civil judgments related to the delivery of healthcare items or services (excluding medical malpractice);

- criminal convictions related to the delivery of healthcare items or services;
- federal or state licensing or certification actions;
- the exclusion of healthcare providers from state or federal healthcare programs; and
- other adjudicated actions that affect or could affect the payment, provision, or delivery of healthcare items or services.²¹

While a primary purpose of the data in the HIPDB is to provide information to state and federal agencies responsible for investigating and prosecuting suspected healthcare fraud cases, the OIG has stated that the HIPDB is intended as a “flagging” system and that the information should only serve as an alert to federal and state agencies and health plans that there may be a problem with a healthcare provider or supplier.²² Health plans and state licensing agencies may query the database to check the qualifications and past actions of healthcare providers.²³

B. Who Must Report to the HIPDB?

Health plans and state and federal agencies must report to the HIPDB. The term “health plan” is defined quite broadly as:

a plan, program or organization that provides health benefits, whether directly, through insurance, reimbursement or otherwise, and includes, but is not limited to—

- (1) A policy of health insurance;
- (2) A contract of a service benefit organization;

Continued on page 22

Continued from page 21

(3) A membership agreement with a health maintenance organization or other prepaid health plan;

(4) A plan, program, or agreement established, maintained or made available by an employer or group of employers, a practitioner, provider or supplier group, third party administrator, integrated health care delivery system, employee welfare association, public service group or organization or professional association; and

(5) An insurance company, insurance service or insurance organization that is licensed to engage in the business of selling health care insurance in a state and which is subject to state law which regulates health insurance.²⁴

“Health plan” also includes a plan made available by an employer or association. Consequently, along with the employer that offers a health benefit plan to its employees, the insurance company, third-party administrator (TPA), or health maintenance organization (HMO) that insures and/or administers the health benefit plan is considered a health plan under the HIPDB regulations. This raises the question of who has to report to the HIPDB: whether the responsible reporting party is the employer that sponsors the health benefit plan, or the insurance company, TPA, or HMO that insures and/or administers it. The HIPDB final rule specifies that the health plan that takes the action must

report it, but the health plan may delegate the reporting function.²⁵

C. What Must Health Plans Report to the HIPDB?

Health plans have to report civil judgments obtained by the health plan against a healthcare provider or supplier related to the delivery of healthcare items or services (excluding medical malpractice actions), and “other adjudicated actions or decisions” that affect or could affect the payment, provision, or delivery of healthcare items or services.

The term healthcare provider or supplier (collectively “provider”) includes nearly every type of healthcare practitioner, facility, and supplier with which a health plan may contract, or for which it provides covered benefits. The definition also includes persons that provide support services to health plans, such as insurance agents and accountants. As a result, in some instances, an MCO may have to report personnel actions if those actions qualify as an “other adjudicated action.”

For example, if a health plan determines that one of its case managers (e.g., a registered nurse) is involved in a scheme with a practitioner to defraud the health plan through the submission and approval of false claims and, as a result, the health plan terminates the case manager’s employment, the health plan may have to report the case manager to the HIPDB if the personnel action qualifies as an adjudicated action.

For purposes of the reporting obligation, “civil judgment” means, other than a criminal action, a court-ordered action rendered in a federal or state

court proceeding.²⁶ The term does not include consent judgments entered into to provide security for a settlement in which there was no finding or admission of liability.²⁷ However, if the health plan terminates the provider from the health plan’s network as a result of the allegations in the lawsuit and the resulting settlement, the termination may be reportable as an adjudicated action, as will be discussed.

1. What is an “Other Adjudicated Action or Decision?”

Arguably, this is the most difficult term for health plans to interpret in order to determine whether a plan action is reportable. An adjudicated action or decision is defined in three parts: (1) a formal or official final action is taken against a provider by a health plan; (2) the action or decision is based on acts or omissions that affect or could affect the payment, provision, or delivery of a healthcare item or service; and (3) the health plan gives the provider access to a due process mechanism to appeal the health plan’s action or decision.²⁸ The definition expressly excludes clinical privileging actions (but see earlier discussion of NPDB), overpayment determinations, and claims denial determinations.²⁹ However, if the basis for the clinical privileging action, overpayment determination, or claims denial determination also results in a personnel action or provider contract termination, the action may be reportable.

The first requirement for an adjudicated action to be reportable is the health plan must render a final decision. The two major categories of

final decisions that health plans make and that may be reportable are provider contract/network decisions (such as contract terminations) and personnel actions. A decision is final when the health plan makes its decision, regardless as to whether the provider or employee appeals the health plan’s decision.³⁰ Note that the health plan must indicate in its report to the HIPDB if the provider is appealing or has appealed the health plan’s decision, as well as the date of such an appeal.³¹

The second requirement is that the health plan’s final decision must be based on acts or omissions by the provider that affect or could affect the payment, provision, or delivery of a healthcare item or service. The OIG, in developing the HIPDB regulations, intentionally made this category broad. “To limit the adverse actions collected by the data bank to only those that are based on health care fraud and abuse would create a data bank that does not fully capture the types of reports that Congress clearly intended to be collected.”³²

Some types of personnel actions and provider contracting decisions clearly are not reportable, such as provider contract terminations without cause (e.g., decreasing the size of the health plan’s provider network), layoffs, or terminations due to insubordination or unexcused absences from work. In addition, some health plan final decisions are based on another entity’s action, and that entity’s action is based on acts or omissions by the provider that affect the payment, provision, or delivery of a healthcare item or service.

Consider, for example, a situation where a provider's license to practice medicine is revoked because of quality of care issues, and a health plan terminates the provider's contract because the provider no longer has a license to practice medicine. In this situation, the state licensing agency would have to report the action to the HIPDB, but the health plan would not, because the health plan's contract termination was not based on a decision by the health plan that related to acts or omissions by the provider related to payment, provision, or delivery of a healthcare item or service. Rather, the health plan's termination was based on minimum criteria necessary to participate in the network, and the health plan did not independently evaluate the facts that resulted in the revocation of the provider's license.

Other examples of health plan actions that are based on credentialing or employment criteria and do not necessarily involve an evaluation by the health plan of the provider's acts or omissions that affect or could affect the payment, provision, or delivery of a healthcare item or service are: the termination of a provider's contract resulting from provider's exclusion from a federal healthcare program; the termination of an employee due to misrepresentation of the level of education in the hiring process; or the termination of a provider's contract because the provider failed to maintain the level of liability or malpractice insurance required by the health plan. Types of health plan actions based on a provider's acts or omissions that affect or could affect the payment, provision, or delivery of a

healthcare item or service include the termination of a provider contract due to member complaints about quality of care, or termination or suspension of an employee based on suspicions of claims fraud.

The third requirement that must be met for a health plan action to be reportable is that the health plan must provide due process to the provider. The regulations appear to require that for an action to meet the definition of an "adverse action" the health plan's review process must meet the requirements for notice and hearing set forth in section 412(b) of HCQIA:

For health plans that are not Government entities, an action taken following adequate notice and the opportunity for a hearing that meets the standards of due process set out in section 412(b) of the HCQIA (42 U.S.C. § 11112(b)) also would qualify as a reportable action under this definition.³³

However, it should be noted that, an HRSA representative has indicated that a health plan's process could satisfy the due process requirements without substantially complying with the HCQIA requirements. The HRSA representative is of the opinion that satisfying the HCQIA requirements is just one way to satisfy the due process requirement in the regulation. In general, HCQIA requires a healthcare entity to give notice to the provider of the entity's proposed action, the provider has a right to request a formal hearing, and the hearing takes place before the healthcare entity takes the proposed action.³⁴ The

hearing must have many of the same requirements as a judicial proceeding, including: the provider's right to have an attorney represent the provider; a formal record of the proceeding; testimony, examination, and cross-examination of witnesses; the right to produce evidence; and the right to submit a written statement at the close of the hearing.³⁵ There are also restrictions on the person or persons that may be a member of the hearing panel.³⁶ The HIPDB regulations do not require that a provider utilize the hearing process for an action to be reportable; it only requires that the health plan have such a process available to the provider.³⁷

Often, health plans' employment and provider network processes do not contain these necessary hearing procedures. If a health plan does not provide the hearing opportunity, it appears the health plan's actions are not reportable to the HIPDB, but see HRSA representative's opinion described above. Reportable personnel actions may occur more frequently in HMOs, because HMOs, especially staff model HMOs, tend to employ more medical personnel, and the personnel action process for medical personnel tends to more frequently comply with HCQIA.

2. If a Health Plan Does Not Let a Healthcare Provider in Its Network, Does the Health Plan Have to Report That Denial?

Technically, a health plan's decision not to admit a provider into the health plan's network could be reportable if the health plan complies with the

three criteria indicated above. Often, however, a health plan's decision not to admit a provider to its network will not satisfy the above criteria, because either the determination is not based on acts or omissions by the provider that affect or could affect the payment, provision, or delivery of a healthcare item or service, or the health plan does not offer the hearing process to healthcare providers denied admission to the health plan's network (typically, if the health plan offers such a hearing process, the process is only available to providers terminated from the network).³⁸

D. What Happens if a Health Plan Fails to Report a Reportable Action to the HIPDB?

Health plans must report civil judgments and adjudicated actions or decisions within thirty days of the judgment or decision, or by the close the health plan's next monthly reporting cycle, whichever is later.³⁹ If the health plan fails to report the judgment or action, the health plan may be subject to a civil money penalty (CMP) of up to \$25,000 for each adverse action not reported.⁴⁰ When determining the amount of the CMP, the OIG will take into consideration the following factors:

- (1) the nature and circumstances of the health plan's failure to report the adverse action(s);
- (2) the degree of culpability of the health plan in failing to provide timely and complete data;
- (3) the significance of the failure to report the information

Continued on page 24

Continued from page 23

to the HIPDB;

(4) any prior history of the health plan related to failure to report; and

(5) any other matters required by justice.⁴¹

It should be noted that HRSA notifies a provider if a report on that provider is filed to the HIPDB and the provider may dispute the report.⁴²

E. Does a Health Plan Have to Query the HIPDB?

Health plans do not have to query the HIPDB before employing or contracting with a provider. However, the OIG's Compliance Guidance for Medicare+Choice (M+C) MCOs⁴³ recommends that M+C MCOs utilize government resources such as the HIPDB to determine whether individuals or entities with whom the M+C MCOs plan to contract or employ are debarred or excluded.⁴⁴

While the HIPDB was created to help fight fraud and abuse and can be a useful tool to health plans, it can create additional burdens for health plans. If health plans fail to report, the failure may potentially result in the imposition of significant money penalties. MCOs should evaluate their personnel and provider contracting practices to determine if a plan action could potentially be reportable. If so, the plan should implement a process by which its actions are evaluated and promptly reported, if necessary.

Endnotes

¹ Office of Inspector General for the U.S. Dep't of Health & Human Services, Report #OEI-01-99-00690

Managed Care Organization Nonreporting to the National Practitioner Data Bank (May 2001)(hereinafter "OIG Report").

² 42 U.S.C. § 11101 and 45 C.F.R. § 60.1 *et seq.*

³ 45 C.F.R. § 60.5.

⁴ 45 C.F.R. § 60.3.

⁵ *Id.*

⁶ Some states require peer review process as a condition of MCO licensure. See, e.g., Md. REGS. CODE tit. 10, § 07.11.04.

⁷ 45 C.F.R. § 60.11.

⁸ *Id.*

⁹ National Committee for Quality Assurance, *Surveyor Guidelines for the Accreditation of MCOs*, ¶ CR 5.1 (July 1, 2001).

¹⁰ *Id.* at 293.

¹¹ Health Resources and Services Admin., U.S. Dep't of Health & Human Serv., *National Practitioner Data Bank Guidebook* (Sept. 2001)(hereafter referred to as the "NPDB Guidebook").

¹² The HRSA is a division within HHS designated by the OIG to administer the HIPDB and NPDB data banks.

¹³ *NPDB Guidebook* at E-17.

¹⁴ 45 C.F.R. § 60.9.

¹⁵ *Id.* § 60.9(a)(2).

¹⁶ *Id.* § 60.9(a)(1).

¹⁷ 42 U.S.C. § 11111.

¹⁸ *Id.* at § 11111(b).

¹⁹ OIG Report at p. 12.

²⁰ National Committee for Quality Assurance, *Surveyor Guidelines for the Accreditation of MCOs* ¶ CR 5.1 (July 1, 2001).

²¹ 42 U.S.C. § 1320a-7e and 45 C.F.R. §§ 31.1 *et seq.*

²² 64 Fed. Reg. 57,740, 57,744 (Oct. 26, 1999).

²³ OIG, *News Release – Healthcare Integrity and Protection Data Bank Set to Launch*, (Oct. 25, 1999).

²⁴ 45 C.F.R. § 61.4.

²⁵ 45 C.F.R. § 61.3 and comments to the HIPDB Final Rule at 57,746.

²⁶ 45 C.F.R. § 61.3.

²⁷ *Id.*

²⁸ *Id.*

²⁹ *Id.*

³⁰ *Id.* at § 61.11(a).

³¹ HRSA, *National Practitioner Data Bank (NPDB) and Healthcare Integrity and Protection Data Bank (HIPDB) Interface Control Document (ICD) for Adverse Actions Report (AAR) Transactions*, (August 23, 1999).

³² 64 Fed. Reg. 57,740, 57,742 (Oct. 26, 1999).

³³ 42 U.S.C. § 11112(b).

³⁴ *Id.*

³⁵ *Id.*

³⁶ *Id.*

³⁷ 64 Fed. Reg. 57,740, 57,748 (Oct. 26, 1999).

³⁸ See 42 C.F.R. § 422.204(c) (requiring Medicare+Choice organizations to only make the provider appeals process available to terminated or non-renewed physicians).

³⁹ 45 C.F.R. § 61.5.

⁴⁰ 42 C.F.R. § 1003.102(b)(5)(ii); 45 C.F.R. §§ 61.9(d) and 61.11(d).

⁴¹ 42 C.F.R. § 1003.106(a)(2) and 63 Fed. Reg. 46,739 (Sept. 2, 1998).

⁴² HRSA, *HIPDB Information Guidebook*, p. F-1 (February 2000).

⁴³ 64 Fed. Reg. 61,893 (Nov. 15, 1999).

⁴⁴ *Id.* at 61,908.

American Health Lawyer Association SISLCs Staff

1025 Connecticut Ave NW
Suite 600
Washington, DC
20036-5405
Phone: 202-833-1100
Fax: 202-833-1105
www.healthlawyers.org

WAYNE MILLER, CAE

Deputy Executive Vice
President/COO
(202) 833-0775
wmiller@healthlawyers.org

EILEEN M. BANTEL

Manager of Special Interest and
Substantive Law Committees
(202) 833-0778
ebantel@healthlawyers.org

Laurie M. Garvey

Special Interest and
Substantive Law
Committees Coordinator
(202) 833-0783
lgarvey@healthlawyers.org

AMERICAN HEALTH LAWYERS ASSOCIATION
HMOs and Health Plans SISLC
Member Survey

1. **SUBSTANTIVE AREAS OF INTEREST:** I would suggest that the HMOs and Health Plans SISLC address the following substantive issues or areas of interest. (Also indicate how you feel each item could best be addressed, e.g., newsletter article, listserve discussion, telephone seminar, member briefing, or other specific project such as a practice guide.)

2. **NEWSLETTER AND SPECIAL MEMBER BRIEFINGS:** I recommend that the HMOs and Health Plans SISLC address the following topics in either a newsletter article or Special Member Briefing:

3. **MID-YEAR AND ANNUAL COMMITTEE MEETINGS:** I recommend that the HMOs and Health Plans SISLC consider the following topics and/or types of programs in conjunction with the Mid-Year and Annual Committee Meetings: (Please also list your preference for speaker, panel discussion, table discussion groups, networking sessions, or other form of presentation)

4. **AFFINITY GROUPS OR TASK FORCES:**

A. I believe that the HMOs and Health Plans SISLC should establish affinity groups (to share ideas and interact with colleagues with similar interests) or task forces (for producing specific projects) to improve networking among members with a particular specialty or interest.

- Yes
 No

B. I would be willing to support and participate in newly created affinity groups/task forces as a:

- Participant
 Co-chair
 Chair

C. Suggestions for scope and activities for affinity groups:

5. **CALL FOR VOLUNTEERS:** I would like to volunteer to participate in the HMOs and Health Plans SISLC work activities in the following ways:

- Author an article for the Newsletter Topic: _____
 Author a Special Member Briefing Topic: _____
 Serve on the Year-in-Review Task Force to identify and prepare attributed notices of analysis of noteworthy case law and trends
 Serve as a speaker for a teleconference Topic: _____
 Assist with monitoring the listserve
 Other Activities or projects:

6. E-SISLC SUGGESTIONS: I suggest the following e-mail or internet based activities for the HMOs and Health Plans SISLC:
Additional links for the HMOs and Health Plans SISLC Web page:

Discussion threads to initiate on the listserve

Topic: _____

Other Web-based activities or projects:

7. ADDITIONAL SUGGESTIONS: I recommend the HMOs and Health Plans SISLC consider sponsoring the following projects/undertakings:

8. OTHER COMMENTS: Please give us any other comments or suggestions you may have about the SISLC program in general, additional SISLCs that might be created, or any other comments you have about the operation of the SISLCs.

9. MEMBER CONTACT INFORMATION:

Name: _____

Firm or Affiliation: _____

Address: _____

Telephone No: _____

Fax: _____

E-mail: _____

Thank you for taking the time to complete this survey. Your input is very important to us!

Please return this survey to:
Laurie Garvey, SISLC Coordinator
American Health Lawyers Association
1025 Connecticut Ave NW, Suite 600
Washington, DC 20036-5405
Fax: (202) 833-1105
E-mail: lgarvey@healthlawyers.org

2001–2002 CALENDAR OF EVENTS

American Health Lawyers Association Educational Programs

MARK YOUR CALENDAR . . . MAKE PLANS TO ATTEND

January 24–25, 2002

Legal Issues Affecting Academic Medical Centers and Other Teaching Institutions

Ritz-Carlton Hotel, Washington, DC

**Special Interest Law Committee Luncheon:*

Teaching Hospitals and Academic Medical Centers—January 25

**Registration fees paid by January 4, 2002:
Member—\$615; Group Member—\$540;
Non-Member—\$765

February 7–8, 2002

Hospitals and Health Systems Law Institute

Doubletree Paradise Valley Resort
Scottsdale, AZ

**Special Interest and Substantive Law Committee Luncheons:*

Credentiailling and Peer Review—February 7
Hospitals & Health Systems—February 7
Healthcare Liability and Litigation—February 8
In-House Counsel—February 8

**Registration fees paid by January 11, 2002:
Member—\$765; Group Member—\$690;
Non-Member—\$915

February 7–8, 2002

Advanced Mediation Techniques

Doubletree Paradise Valley Resort
Scottsdale, AZ

Member—\$795; Non-Member—\$995

To register or for more information on mediation training, call 202-387-4176 or e-mail
jjohnson@cdsusa.org

February 27–March 1, 2002

Long Term Care and the Law

Sheraton New Orleans Hotel
New Orleans, LA

**Substantive Law Committee Luncheons:*

Long Term Care—February 28
Labor, OSHA, and Human Resources—March 1

**Registration fees paid by February 5, 2002:
Member—\$745; Group Member—\$670;
Non-Member—\$895

April 3–5, 2002

Institute on Medicare and Medicaid Payment Issues

Baltimore Marriott Waterfront Hotel, Baltimore, MD

**Substantive Law Committee Luncheons:*

Physician Organizations—April 3
Regulation, Accreditation & Payment—April 4
Antitrust—April 5

**Registration fees paid by March 26, 2002:
Member—\$780; Group Member—\$705;
Non-Member—\$930

May 7-8, 2002

Managed Care Law Institute

(co-sponsored with the American Association of Health Plans)

Broadmoor Hotel, Colorado Springs, CO

**Substantive Law Committee Luncheon:*
HMOs and Health Plans

May 16–17, 2002

ADR Mediation Essentials Training: Practical and Theoretical Approaches to Effective Mediation of Healthcare Disputes

The Carnegie Endowment for International Peace, Washington, DC

Member—\$795; Non-Member—\$995

To register or for more information on mediation training, call 202-387-4176 or e-mail
jjohnson@cdsusa.org

June 30, 2002

In-House Counsel Program

San Francisco Marriott Hotel, San Francisco, CA

**Special Interest Committee Luncheon:*
In-House Counsel (included in program registration fee)

Registration Fees:
Member—\$275; Non-Member—\$425

July 1–3, 2002

Annual Meeting

San Francisco Marriott Hotel, San Francisco, CA

**Special Interest and Substantive Law Committees Luncheons*

Monday, July 1, 2002—Antitrust; Fraud and Abuse, Self-Referrals, and False Claims; Teaching Hospitals and Academic Medical Centers; Healthcare Liability and Litigation; Tax and Finance

Tuesday, July 2, 2002—Health Information and Technology; Long Term Care; HMOs and Health Plans; Physician Organizations

Wednesday, July 3, 2002—Credentiailling and Peer Review; Labor, OSHA, and Human Resources; Hospitals and Health Systems; Regulation, Accreditation, and Payment

**Registration fees paid by May 30, 2002:
Member—\$895; Group Member—\$820;
Non-Member—\$1,045; Celebration Sale—\$820

*All Special Interest and Substantive Law Committee (SISLC) luncheons cost an additional \$37 per luncheon. All attendees are welcome to register for the luncheons which feature topic presentations and offer networking opportunities.

**Registration fees increase by \$75 after this date. AHILA is currently accepting registrations for those AHILA programs with confirmed dates and locations. Please see registration form on page 28. Please watch *Health Lawyers News* and our Web site to register and for details on these programs.



1025 Connecticut Ave, NW, Suite 600
Washington, DC 20036-5405
Phone: (202) 833-1100
Fax: (202) 833-1105
www.healthlawyers.org

Register Now!

Teleconferences

Bankruptcy: HMOs, Risk-Bearing Contractors and Providers

January 16, 2002 1 - 3 pm

*Co-sponsored by Healthcare Liability and Litigation,
HMOs and Health Plans, and Physician Organizations*

Managed Care Contracting

Payor - January 29, 2002

Providers - January 30, 2002

1 - 2:30 pm

*Co-sponsored by Hospitals and Health Systems,
HMOs and Health Plans, and Physician Organizations*

Register at www.healthlawyers.org/teleconferences.cfm or call (202) 833-0766

HMOs
& Health Plans
Winter 2001 Volume 4 Issue 2