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Issues - Consumer Bill of Rights

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the National Association of People with AIDS

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November 17, 1997

The Honorable Donna E. Shalala, Ph.D.
Secretary of Health & Human Services
The Hubert H. Humphrey Building
200 Independence Avenue, S.W., Suite 615F
Washington, D.C. 20201

Dear Secretary Shalala:

I am writing with regard to the progress of the President's Commission on Consumer Protection and Quality in the Health Care Industry and as a follow-up to correspondence from the National Association of People with AIDS (NAPWA) sent to you on October 17, 1997. NAPWA has closely monitored the Commission's progress over the last few weeks and believes the draft Consumers Bill of Rights has been significantly improved since I last wrote to you. Your proposal, however, still falls far short of a true Bill of Rights capable of providing meaningful protection to consumers. This letter seeks to address a few areas where there is still an opportunity to make improvements.

NAPWA is deeply concerned that the ad hoc group on nondiscrimination that met in Washington on November 3rd was unable to reach consensus on the fundamental right that all Americans should be free from discrimination based on health status whenever they interact with the health care system. In our current health care system, all of us are vulnerable to being completely shut out of a system of care--or, once entering, to having health care providers willfully design their health care "products" with the deliberate intention of not providing the level of care or set of benefits that specific types of sick people need. It is disappointing that a distinguished body of individuals selected by the President for their leadership in the health arena could not imagine a future where the widespread discrimination experienced today by the thousands of people living with HIV disease and the millions of people with disabilities would no longer exist. Notwithstanding this and other concerns about the Commission's work thus far, NAPWA strongly urges you to accept a document called a "Bill of Rights" only if it contains provisions in two critical areas wherein agreement on the Commission is still possible: protecting insurance coverage for persons participating in clinical trials and the establishment of independent consumer assistance programs.

First, throughout our nation's history of fighting the HIV epidemic, people living with HIV have recognized the importance of biomedical research to their own survival. This recognition has produced an informed group of people willing and eager to support research by participating in clinical trials.

October 17, 1997

The Honorable Donna E. Shalala
Secretary of the U.S. Department of Health & Human Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W.
Washington, D.C. 20201

NAPWA

NATIONAL ASSOCIATION OF PEOPLE WITH AIDS

Dear Dr. Shalala:

The National Association of People With AIDS (NAPWA) serves as the national advocacy and resource organization for people living with HIV/AIDS in the United States. In this capacity, NAPWA has placed a high priority on working to improve access to high quality comprehensive health care. NAPWA was pleased when the President announced the formation of the President's Advisory Commission on Consumer Protection and Quality in the Health Care System. We were particularly encouraged that a "Consumer Bill of Rights" was to be a key outcome. Further, we were heartened by the establishment of the Subcommittee on Consumer Rights, Protections and Responsibilities, and its charge to take the lead on the development of the Bill of Rights. Therefore, we have carefully monitored the activities of the Commission. A major area of concern for NAPWA and people living with HIV, is to ensure that the Commission produces a Bill of Rights that is legally enforceable.

From the preliminary materials we have seen, there are several positive aspects to the draft "Consumer Bill of Rights." NAPWA is pleased that the Bill of Rights applies to all consumers, regardless of how they obtain health care services. We are also encouraged to see that it provides for external review of health plan decisions, provides for a ombudsprogram, and includes a non-discrimination provision. Further, there are several specific provisions of which NAPWA is supportive. As we observe the operation of the Subcommittee, however, we are deeply concerned that consumers and consumer's representatives are not adequately represented on the Advisory Commission. Additionally, since the Subcommittee has been instructed to work within a consensus structure, we are even more uncertain that the limited number of consumer advocates participating will be able to achieve consensus on a Bill of Rights that can adequately protect all consumers.

We recognize that the health care industry and the business community are critical partners with consumers in structuring a health care system that provides high quality care, equitably and efficiently. Nonetheless, the interests of the for-profit health sector and the business community are often in opposition to consumers - especially vulnerable consumers with complex conditions and health care needs. We are extremely concerned that an eventual outgrowth of the Commission's actions could be a "Consumer Bill of Rights" that neither NAPWA nor the vast majority of America's health care consumers could support.

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In order to strengthen the "Consumer Bill of Rights" and make it a meaningful document to protect consumers, it must be clear that its components are to be enacted into a federal law that provides for their regulation and enforcement. Voluntary guidelines or recommendations are an insufficient response to the concerns and experiences of consumers that have made the work of this Commission necessary. Further, the following specific provisions, while not exhaustive, are critically necessary to protect consumers:

- A consumer's right to information must require that the information be made available in an accessible place and within a specific time-frame.
- Information on drug formularies must describe the process for including new treatments and must provide for off-label uses.
- Provisions for access to clinical trials and experimental treatments must be included.
- For persons with complex conditions, provisions must be made for specialists as the gatekeeper.
- A clear delineation of network adequacy requirements is important.
- Information requirements on network characteristics must require information about language access, physical accessibility, and how specialty and sub-specialty care will be provided.
- Provisions must require plans to meet accessibility standards of the Americans with Disabilities Act (ADA).
- Provisions must provide comprehensive due process protectors for providers.
- Provisions must protect safety-net providers from discrimination.
- Requirements for the prompt resolution of grievances with specific time-frames, are required.
- Plans must disclose information regarding their decision-making process (reporting?) denials of care, and there must be a clear standard for decision-making for external reviewers.
- Medicaid beneficiaries must not be required to exhaust internal plan grievance procedures before they may seek a fair hearing.
- Requirements to use a plan's internal complaint and approval process must not limit consumers ability to contact regulators, the media, or other parties that may assist with the resolution of a complaint.
- The obligation to "avoid knowingly spreading disease and minimize high-risk behavior" must be clarified.

NAPWA urges you, as Commission Chairs, to assert your leadership to ensure that the "Consumer Bill of Rights" will provide consumers with the extensive protection they need. If NAPWA may assist you in achieving this goal, or if you have any questions regarding our recommendations, please contact Jeffrey Crowley, Deputy Executive Director for Programs at 202.898.0414.

Sincerely,

A. Cornelius Baker
Executive Director

cc: Advisory Commission Members & Executive Staff
Sandy Thurman, Director, White House Office on HIV/AIDS

March 13, 1998

Commission Declines to Endorse Legislation Enforcing Patients' Rights

Related Article

- Clinton to Call for Extensive Regulation of Health Plans (Nov. 20, 1997)

By ROBERT PEAR

WASHINGTON -- In a setback for the White House, a presidential advisory commission declined on Thursday to endorse legislation to protect and enforce the rights of patients who have been improperly denied health care benefits promised by insurance companies and employers.

The panel agreed without dissent on the need for a renewed commitment to improving the quality of health care in America. But it left open the possibility that voluntary efforts could achieve that goal without new federal laws.

At its final meeting on Thursday, the 34-member panel sidestepped the politically explosive question of whether to authorize compensation or create additional legal remedies for patients who suffer at the hands of insurance companies and health maintenance organizations.

The panel, headed by the Secretaries of Labor and of Health and Human Services, included representatives of the insurance industry, as well as consumer advocates, doctors, nurses, lawyers, business executives, and labor union leaders.

The panel worked by consensus, requiring virtual unanimity for any major recommendation, and there was nothing approaching unanimity on the issue of enforcement.

Chris Jennings, a White House aide, welcomed the commission's report, but said its recommendations should be enacted into law.

"The commission recommended that consumer protections be provided to all Americans," Jennings said. "The president believes that cannot be achieved without federal legislation."

The battle now shifts to Congress, where Democrats and some Republicans insist that new laws are needed to define and enforce patients' rights.

The proposed bill of rights would provide patients with access to medical specialists and emergency room services, protect the confidentiality of medical records and establish procedures for patients to appeal the denial of health benefits.

President Clinton plans to intensify his push for legislation when he accepts the commission's report at a White House ceremony on Friday, his aides said. Three days ago, Speaker Newt Gingrich said that Congress would probably pass "some kind of patient protection bill" this year.

Consumer advocates, doctors, and some labor leaders on the commission argued that the federal government must regulate health insurance, as it regulates television or the securities industry in the public interest. Insurance executives and employers of all sizes opposed new regulation, saying it would raise the cost of coverage so that more people would be uninsured.

However, the Congressional Budget Office said that compliance with the bill of rights would raise employers' health insurance premiums by just .75 percent, on average. The budget office estimated that employers will spend $288 billion on health benefits this year. In its final report, the commission watered down earlier language that called for new laws to deter "egregious behavior by health plan sponsors and administrators."

Instead, the panel said that "policy makers should engage in a national dialogue regarding the state of existing remedies for individuals in public or private plans who are injured as a result of inappropriate health care decisions."

Donna E. Shalala, the secretary of health and human services, put the best face on the outcome, saying the panel had fostered "civilized discussion" on issues of transcendent importance to consumers.

But Kathleen Sebelius, the insurance commissioner for Kansas, said "we reached a fundamental roadblock, there was no consensus" on how to enforce the patients' bill of rights.

On Capitol Hill, Sen. Don Nickles of Oklahoma, the assistant Republican leader, said: "The commission, unlike the president who appointed its members, did not call on Congress to enact the patients' bill of rights into law."

Donald A. Danner, vice president of the National Federation of Independent Business, seized on the impasse as evidence that government "mandates are the wrong prescription for America's health care system." But his judgment that Clinton's push for legislation to enforce the bill of rights had come to "a screeching halt" seemed premature.

The commission's report said that "licensing, accreditation, and certification organizations have experience" in monitoring compliance with health care standards. So, it said, it is reasonable to expect them to assess compliance

with the bill of rights as well.

A separate advisory panel, studying ways to save the Medicare program, met last week for the first time. The head of that panel, Sen. John B. Breaux, D-La., has said that Congress should defer action this year on Clinton's proposal to open Medicare to people 55 to 64. But White House officials continue pressing Congress to approve the change.

In an interview, Alexis Herman, the secretary of labor, said Congress should expand the legal rights of more than 120 million Americans in employer-sponsored health plans. But the commission on health care quality declined on Thursday to endorse changes in the landmark law that regulates such plans, the Employee Retirement Income Security Act of 1974, known as Erisa.

Dr. Thomas R. Reardon, a commissioner who is chairman of the American Medical Association, said: "I am disappointed that we didn't deal with the Erisa issue more explicitly." Gerald W. McEntee, president of the American Federation of State, County and Municipal Employees, agreed.

Ronald F. Pollack, executive director of Families USA, a consumer group, said the 1974 law "creates a virtual license to wrongfully deny or delay care," because an employer-sponsored health plan generally cannot be sued for damages that result from such denials.

But in an interview, J. Randall MacDonald, executive vice president of the GTE Corp., disagreed.

Asked whether legislation was needed to define patients' rights, MacDonald, a commission member, said: "I don't think it's desirable. I don't think it's necessary. More than 60 million Americans will soon see the patients' bill of rights implemented on a voluntary basis by employers and health plans. Why do I need legislation when the market and people participating in that market are doing it voluntarily?"

When Clinton received the bill of rights from the commission in November, he urged employers to adopt it voluntarily. And GTE did so immediately.

In its final report on Thursday, the panel proposed creation of two bodies, one public and one private, to monitor and promote quality in the health care industry. In addition, it said that measures of quality should be standardized so that consumers and employers could, for example, compare the performance of health plans in immunizing children or screening women for breast cancer.

PRESIDENT CLINTON RELEASES NEW REPORT AND URGES CONGRESS TO PASS PATIENT BILL OF RIGHTS, COMPREHENSIVE TOBACCO LEGISLATION, AND THE MEDICARE BUY-IN PROPOSAL
March 9, 1998

In a speech to the American Medical Association (AMA) today, the President renewed his call to Congress to pass a patients' bill of rights, comprehensive tobacco legislation to reduce teen smoking, and his proposal to allow hundreds of thousands of Americans ages 55 to 65 to buy into Medicare. In his speech, which marks the first time a President has spoken to the AMA in fifteen years, President Clinton highlighted that he and the AMA are united on the need for a patients' bill of rights and tobacco legislation, and urged the AMA to lend its strong support to his Medicare buy-in proposal. Underscoring the bipartisan support for a patients' bill of rights, the President released a report showing that 44 states -- including 28 states with Republican Governors -- have enacted the "Consumer Bill of Rights" that the President's Quality Commission recommended and the President endorsed last year. In his speech, the President:

RELEASED NEW REPORT SHOWING THAT 44 STATES -- INCLUDING 28 STATES WITH REPUBLICAN GOVERNORS -- HAVE ENACTED AT LEAST ONE OF THE PROVISIONS IN THE PATIENTS' BILL OF RIGHTS. The President released a new report that underscores the bipartisan support for the patients' bill of rights he endorsed last year. Highlights from this report are as follows:

- **Forty-four states have enacted at least one of protections in the patients' bill of rights.**

- **Patient protection laws have been enacted by Democratic and Republican Governors alike.** Twenty-eight of the 32 states with Republican Governors have enacted at least one of these protections.

- **Each of these patient protections has been enacted in at least eight states around the country and some have been enacted in as many as forty-one states.** For example:

  -- Twenty-eight states -- including 16 with Republican Governors -- have enacted protections to assure access to emergency room services.

  -- Thirty states -- including 15 with Republican Governors -- have enacted protections to give direct access to certain specialists, including access to qualified specialists for women's health services.

URGED CONGRESS TO PASS FEDERAL LEGISLATION BECAUSE, DESPITE STATE LAWS, STATES HAVE NO JURISDICTION OVER MORE THAN 100 MILLION

AMERICANS. A patchwork of non-comprehensive state laws cannot provide Americans with the protections they need -- especially because state laws do not even have jurisdiction over more than 100 million Americans. For example, they do not cover tens of millions of Americans in self-insured plans covered under the Employee Retirement Income Security Act (ERISA). The only way to ensure that all health plans serving all Americans provide the protections envisioned by the Quality Commission is to pass and enact bipartisan Federal legislation.

CALLED ON CONGRESS TO PASS COMPREHENSIVE TOBACCO LEGISLATION THIS YEAR. The President also reiterated his call for Congress to pass comprehensive tobacco legislation this year that includes his five key principles:

- A comprehensive plan to reduce youth smoking, including: significant price increases; tough penalties on tobacco firms that continue to market to youths; public education and counter advertising; and expanded efforts to restrict access and limit appeal.

- Full authority of the Food and Drug Administration to regulate tobacco products.

- Changes in how the tobacco industry does business, including an end to marketing and promotion to children and broad document disclosure.

- Progress towards other public goals, including a reduction of secondhand smoke; promotion of cessation programs; public health research; and the strengthening of international efforts to control tobacco.

- Protection for tobacco farmers and their communities.

REITERATED THAT THIS TOBACCO PROPOSAL COULD PREVENT UP TO ONE MILLION PREMATURE DEATHS OVER THE NEXT FIVE YEARS. The recent Treasury Department's study, based on conservative estimates from well-respected analytical models, concluded that the Administration's proposal to increase the price of cigarettes by $1.50 per pack -- coupled with proposed sales and advertising restrictions -- would:

- Keep up to 1.9 million Americans from smoking in 2003 -- a 39 to 46 percent reduction in youth smoking. Over the next five years, the cumulative number of young people kept from smoking would be up to 2.8 million.

- The direct result of these policies over the next five years is that as many as 1 million of today's young people will be spared from premature deaths resulting from smoking-related diseases.

URGED CONGRESS TO ACT NOW TO PASS HIS TARGETED PROPOSAL TO GIVE AMERICANS AGES 55 TO 65 ACCESS TO HEALTH INSURANCE.

- **Americans ages 55 to 65 are one of the most difficult to insure populations:** they have less access to and a greater risk of losing employer-based health insurance; and they are twice as likely to have health problems.

- **The President has a carefully-targeted, fiscally-responsible proposal that would allow hundreds of thousands of vulnerable Americans to gain access to more affordable health care coverage by:** allowing Americans ages 62 to 65 to buy into the Medicare program; allowing displaced workers age 55 and over a similar buy-in option; and allowing Americans 55 and over who have lost their retiree health benefits to buy into their former employers' health plan.

- **The Congressional Budget Office just confirmed that this proposal will help hundreds of thousands of Americans without burdening the Medicare Trust Fund or the budget.**

PRESIDENT CLINTON RELEASES WHITE HOUSE REPORT REVEALING THAT STATES HAVE ENACTED EACH OF THE PATIENT PROTECTIONS HE HAS ENDORSED -- INCLUDING MANY STATES WITH REPUBLICAN GOVERNORS
March 9, 1998

- **Thirty-four states -- including 21 states with Republican Governors -- have enacted information disclosure provisions.** At least 34 states have enacted provisions that require health plans to disclose information to help consumers make informed decisions about their health plans, health professionals, and health facilities.

- **Ten states have enacted provider network adequacy provisions -- including four states with Republican Governors.** At least ten states have enacted provisions to help ensure that health plan networks provide access to sufficient numbers and types of providers without unreasonable delay.

- **Thirty states -- including 15 states with Republican Governors -- have enacted protections to give direct access to certain specialists, including qualified specialists for women's health services.** At least 30 states have enacted provisions to give patients greater access to needed specialists, including giving women greater access to qualified specialists for women's health services.

- **Seventeen states have enacted continuity of care protections -- including ten states with Republican Governors.** At least 17 states have enacted protections to help ensure continuity of care for enrollees who are involuntarily forced to change providers.

- **Twenty-eight states have enacted protections to assure access to emergency room services -- including 16 states with Republican Governors.** At least 28 states have enacted legislation to help ensure that patients have access to emergency room services when and where the need arises. These provisions require health plans to pay for the initial screening examination and stabilization care -- regardless of whether the emergency room is in the plan's network -- when an enrolled person needs emergency services. Twenty of these states require the use of a prudent layperson standard to determine whether an emergency exists, to ensure that any person who reasonably thought they were having an emergency is covered by their health plan.

- **Forty-one states have enacted anti-gag clauses -- including 26 states with Republican Governors.** At least 41 states have enacted "anti-gag" clauses prohibiting health plans from using contract clauses that restrict providers' communications with their patients.

- **Eighteen states have enacted provisions that require health plans to disclose financial incentives -- including 12 states with Republican Governors.** At least 18 states have passed protections requiring health plans to disclose any financial arrangements with their physicians.

- **Nineteen states have enacted provisions to protect confidentiality of health information -- including ten states with Republican Governors.** At least 19 states have enacted some type of provision to help protect the confidentiality of health information for health plan enrollees

- **Eight states have enacted anti-discrimination provisions, including six states with Republican Governors.**

- **Twelve states now require that health plan enrollees have access to an external appeal process, including eight states with a Republican Governor.** At least 12 states now require that health plan enrollees have access to specially designated and independent external appeals entities, which are funded and empowered to hear and act upon such appeals.

Last November the President endorsed the "Consumer Bill of Rights" recommended

by his Advisory Commission on Quality and Consumer Protection. These rights included: information disclosure; a choice of providers including provider network adequacy provisions, access to specialists (including qualified specialists for women's health services), and transitional care provisions; access to emergency room services; participation in treatment decisions including prohibiting anti-gag clauses and requiring disclosure of financial incentives; protection of the confidentiality of health information; anti-discrimination provisions; and access to an appeals process.

Todd A. Summers
01/13/98 07:58:59 PM

Record Type: Record

To: Sarah A. Bianchi/OPD/EOP

cc:
Subject: Thoughts on Consumer Bill of Rights

Here are some thoughts on the consumer bill of rights as it relates to people living with HIV/AIDS. Thought you might be interested. Can you tell me what the internal process is for dialogue on where we go with this?

CONSUMER BILL OF RIGHTS
Concerns Related to Persons Living with HIV/AIDS

Section 1: Information Disclosure

- What are the covered benefits?
- Is there prescription drug coverage? If so,
  - what is the covered formulary? If it's limited, how and when is it updated?
  - are there any additional requirements/hurdles to receive combination therapies?
  - are there any price limits or maximum benefit limits?
  - are experimental drugs or off-label use of approved drugs covered?
- Is the AIDS-related experience of health care providers or facilities available?

Section 2: Provider Choice

- Is access provided to an HIV specialist?
- Can an HIV specialist be a primary care physician?
- Within related specialty fields, does the consumer have access to information about the HIV-related expertise of providers?

Section 4: Participation in Treatment Decisions

- Are consumers provided with the time and assistance to actively participate in the often complicated treatment decisions required to manage and treat HIV and AIDS?

Section 6: Confidentiality

- Are health care workers obligated to protect the confidentiality of patient information, including HIV status?
- Any notion of capitated rates, particularly stepped capitation, means increased requirements of information disclosure in order to justify the capitation level of consumer

Section 7: Complaints and Appeals

- Are there any standards for the timeliness of complaint resolution, since many consumers with HIV/AIDS may have limited lifespans?

ECEMBER 15, 1997 CQ NEWSALERT WWW.CQ.COM/NEWS

CQ MONITOR

Legislative News and Information from Congressional Quarterly

Foes of Patients' Rights Bill To Rely On GOP Leadership

Worried about the measure's Popularity, coalition will skip TV ads, play the inside game

Don't look for Harry and Louise when the debate over managed care starts heating up on Capitol Hill next year. They won't be back.

After President Clinton unveiled his comprehensive health care initiative in 1993, the two characters appeared in a series of TV spots talking about how the plan would harm ordinary folks like themselves. But Bill Gradison, president of the Health Insurance Association of America, which sponsored the ads, said the managed-care issue doesn't lend itself well to a "Harry and Louise" rerun.

THE PULSE OF CONGRESS

He said the American Association of Health Plans, a managed-care group, tested issue ads in selected TV markets and found they had "a positive influence" on public opinion — but only until "the next horror story" about denials of care hit the news.

"I don't think [a Harry and Louise ad campaign] fits this issue at all," Gradison said last week.

Instead, Gradison said, HIAA, other insurers and employer groups have formed a coalition to try to head off legislation (HR 1415, S 644) giving patients broader access to specialists, coverage of emergency care that a "prudent layperson" would consider necessary and appeals to independent reviewers when their health plans refuse to pay for care.

Asked to sum up the coalition's strategy, he quipped, "There's a lot to be said for 'Just say no.'"

Gradison conceded there are "a lot of pressures coming together" in favor of regulatory legislation — from doctors, consumer groups and President Clinton, who is expected to urge enactment of a "patient bill of rights" when he delivers his State of the Union address Jan. 27.

At a strategy session last month called by a top aide to Senate Majority Whip Don Nickles, Okla., Gradison advised Republicans to "keep your powder dry" and avoid taking a position that could draw fire during the election campaign.

Opponents will rely on Republican leaders in both chambers to keep managed-care bills bottled up in committee. "Once these bills hit the floor, it's real hard to oppose them," he said.

In the House, HR 1415 faces referral to three committees — Commerce, Education and the Workforce, and Ways and Means. While the bill might get out of Commerce, where chief sponsor Charlie Norwood, R-Ga., is a member, it faces a more hostile Republican audience in the other two panels.

In the Senate, Majority Leader Trent Lott, Miss., can refuse to call up the managed-care bill, but any senator can offer it as an amendment to unrelated legislation. Asked if he'd like to keep the bill off the floor altogether, Gradison grinned: "That would be marvelous."

— Chuck McCutcheon

SFAF HIV Policy Watch, Nov./Dec. 1997

The HAAC also began a discussion of its role in the second reauthorization of the CARE Act, which will start in FY 1999. The HAAC's next meeting will be in March 1998. For more information, call HRSA's Division of Training and Technical Assistance at 301/443-9530.

President Receives "Bill of Rights" From Quality Commission

On November 20th, President Clinton's Commission on Consumer Protection and Quality in the Health Care Industry unveiled a Consumer Bill of Rights, designed to protect consumers in today's managed care environment. Upon receipt of the report, President Clinton called on Congress to enact legislation implementing the Bill of Rights.

The 32 member advisory commission is comprised of representatives of all key stakeholders in the health care system, including consumers, providers, insurers, and employers. The commission is chaired by Labor Secretary Herman and Health and Human Services Secretary Shalala. Dr. Sandra Hernandez, San Francisco's former Director of Public Health and presently President of the San Francisco Foundation, serves on the Commission.

From a consumer perspective, the Bill of Rights is good news, but not as great as we had hoped it would be. Because the drafting process was predicated on achieving consensus between Commissioners whose own interests may conflict with those of consumers, numerous important critical issues were not addressed. These include adapting the current managed care financing system to take away strong incentives to not serve people with HIV and others with high-cost conditions. In other areas, the consensus achieved on issues that the Commission spent a great deal of time discussing was disappointing. For example, the Commission could not agree that consumers should be free from discrimination whenever they interact with the health care system. They also could not agree that persons who participate in clinical trials have a right to the health care benefits from their insurer for which they otherwise qualify if they did not participate in a clinical trial.

The good news about the work of the Commission, however, is that this diverse group of individuals, including representatives of employers and the health insurance industry, acknowledged that consumers face significant barriers to obtaining quality care. They also agreed that basic protections are essential to improve quality and access--and to increase confidence in the health care system. Perhaps the Bill of Right's most significant victory for consumers was an agreement that when consumers have problems in accessing care from their health plan, they should have a right to file an external appeal, where a party independent of the plan would be asked to review the consumer complaints.

Given the fractious environment over health care reform in this country, most observers believe that the political consensus achieved by this diverse group of interests is a positive step forward. Nonetheless, no Bill of Rights will protect consumers unless it is enacted into law. Our agenda for 1998 must include working with our allies in Congress to take the spirit of the Bill of Rights and pass a law that will give consumers meaningful new protections. In so doing, the AIDS Foundation will continue to work with the National Association of People with AIDS and other consumer groups.

CMA Likely to Introduce Names Reporting Bill in 1998

As the HIV surveillance debate continues to grow, California is poised to become one of the major battlegrounds in the year ahead. Earlier this year, the California Medical Association (CMA) passed a resolution to sponsor state legislation mandating HIV names reporting. This

FAX TRANSMISSION COVER SHEET

AIDS Action council

TO: Todd Summers

FROM: Amy Andersen, ext. 3028

DATE: November 19, 2997

RE: Comments on Draft Consumer Bill of Rights

NUMBER OF PAGES (including cover): 12

* *

Todd – I've attached the two letters that AIDS *Action* sent to the President's Advisory Commission on key issues of concern to people living with HIV/AIDS. In addition, I've attached the letter that AIDS *Action* and numerous other consumer and provider groups sent today to the President.

Let's plan on getting together after December 1st to talk about consumer quality protections and HIV/AIDS. I really think that the HIV/AIDS community can add some unique perspectives to legislative debates on managed care consumer protections that ultimately can benefit all consumers.

See you tomorrow!

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Fax 202 986 1345
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If you experience difficulty in receiving this fax, please call (202) 986-1300.

AIDS Action council

October 17, 1997

The Honorable Alexis Herman
The Honorable Donna Shalala
Co-Chairs, President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry
Hubert H. Humphrey Building
200 Independence Avenue, SW, Suite 118-F
Washington, DC

Dear Secretaries Herman and Shalala:

AIDS *Action*, the national voice on AIDS representing 2,000 community service organizations and the one million HIV-positive persons they help serve, has been closely monitoring the work of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. AIDS *Action* was pleased when the President announced the formation of the Advisory Commission and was particularly supportive of Advisory Commission's charge to develop a Consumer Bill of Rights and Responsibilities. The Consumer Bill of Rights and Responsibilities may serve as a foundation for consumer protections and health care quality in both the private and public health care markets. Because of this, AIDS *Action* wants to ensure that the Bill of Rights appropriately protects the special health care needs of vulnerable, high-cost populations like people living with HIV/AIDS.

Inclusion of public health care market (Preamble, p. 3)
People living with HIV/AIDS inordinately rely on public entitlement programs for their health care – over 53% of adults with AIDS and over 90% of children with AIDS rely on Medicaid for health care coverage. As people with HIV/AIDS live longer, increasing numbers are dually eligible for Medicaid and Medicare. We support the intent of the Commission to develop consumer and quality protections that would apply to both the private and public health care markets. We cannot exempt public entitlement programs like Medicaid from consumer protections and create a two-tiered health care system protecting some populations and not others. We, therefore, urge the Commission to keep the scope of the Bill of Rights broad and grant all consumers equal rights.

Special health care needs of vulnerable populations (Preamble, p. 4)
AIDS *Action* commends the Commission for recognizing the special needs of vulnerable health care consumers. We suggest that the definition of vulnerable populations needs to explicitly include consumers with high-cost health care needs, like people living with HIV/AIDS. The Commission recognizes that the Americans with Disabilities Act (ADA) of 1990 and the Health Insurance Portability and Accountability Act of 1996 were significant moves forward for consumer access and protection. However, these laws do not address some of the economic barriers that prevent many vulnerable consumers from maintaining, receiving, or acquiring

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quality health care. Raising lifetime caps on health care coverage in the private health insurance market, for example, would help many vulnerable consumers maintain their health insurance and prevent them from becoming impoverished by their illness in order to receive public assistance.

Other solutions to mitigate the economic barriers in the health care market relate to the relationship between reimbursement, quality, and access to care. For the public and private managed care market, adequate or enhanced capitation rates for vulnerable populations may help ensure access to quality of health care. Risk adjustment across a given plan offers another valuable tool to ensure that health care plans don't ration care to individuals with high health care costs.

Access to care (Chapter II, p. 1)
AIDS *Action* acknowledges the strides made by the Commission to delineate the rights of consumers to access appropriate high-quality care. Rightly, the Commission recognizes the special needs of certain populations under managed care and other coordinated health delivery systems. We recommend that the Commission clarify the conditions under which "consumers with complex or serious medical conditions" would have access to specialized care. We believe that all individuals with HIV disease, symptomatic or asymptomatic, meet the definition of "complex or serious medical condition."

- The complicated nature of HIV/AIDS treatment requires the clinical management of providers with HIV/AIDS expertise. Therefore, we recommend that the Commission explicitly allow people with HIV/AIDS and other individuals with complex health care conditions to designate a provider with specialized HIV/AIDS expertise as their "gatekeeper". A article recently published in the *Journal of the American Medical Association* highlights the critical relationship between provider HIV/AIDS expertise and effective HIV/AIDS patient care.[1] (Attachment)
- Direct access to specialists should include "standing referrals" without inordinately limiting the number of visits.
- Health plans should also allow consumers to access medically necessary specialized care "out of plan" at no additional cost, if the health plan is unable to deliver the necessary care.

Non-discrimination (Chapter V, p. 1)
People living with HIV/AIDS have long experienced discrimination in all areas of their lives, including the health care environment. We commend the Commission for including non-discrimination so prominently within the draft Bill of Rights. While the Commission includes a reference to the ADA in its rationale section, the statement of the non-discrimination does not explicitly track the ADA. Therefore, AIDS *Action* recommends that the non-discrimination provision be amended to read:

> "Consumers must not be discriminated against in provision of health care services based on race, ethnicity, national origin, religion, sex, age, current, **perceived,** or anticipated mental or physical disability, sexual orientation, genetic information, or source of payment." ***(bold indicates change)***

[1] Sharpe, VL, Zuger, A. "HIV Specialists": The Time Has Come. *JAMA*. 1997; 278; 1131-1132.

AIDS *Action* also suggests that the Commission clarify that the non-discrimination protections also extend to health care providers.

Confidentiality of health information (Chapter VI, pp. 1-3)
AIDS *Action* commends the Commission for recognizing the lack of federal protections currently in place to protect the privacy and confidentiality of health information. We believe that strong federal privacy laws must be enacted to protect consumer health information – particularly for vulnerable consumers including people living with HIV/AIDS. Stringent enforcement measures, including monetary sanctions and penalties, are key to ensuring compliance with confidentiality/privacy regulations or law. We recommend that the Commission strengthen the enforcement and security provisions in the Bill of Rights to prevent breaches of confidentiality.

Clinical research has provided people living with HIV/AIDS and other vulnerable populations with life-saving breakthroughs in treatment. AIDS *Action* acknowledges the significant contributions of biomedical research and consequently does not intend to advocate for confidentiality/privacy regulations or laws that would infringe research outcomes. However, the draft Bill of Rights allows researchers too much flexibility in accessing and disclosing individually-identifiable health information. AIDS *Action* recommends that the Commission explicitly require researchers to:

- Obtain informed consent as a condition of conducting research involving individually-identifiable health information.
- Demonstrate to their Institutional Review Board or other authorizing body a rationale for using individually-identifiable health information in their research project.

Complaints and appeals (Chapter VII, p. 1)
Mechanisms for dispute resolution are particularly important for individuals with complicated health care needs and other vulnerable populations. The Commission's work on complaints and appeals is essential to ensuring that all health care consumers have access to appropriate and fair dispute resolution mechanisms. AIDS *Action* recommends that the Commission add more specificity in expedited review periods. Interruptions in ongoing HIV/AIDS treatment can result in disastrous complications, severely compromising care. AIDS *Action* recommends that:

- Expedited review should not be limited to emergency or urgent care.
- Treatment should be continued during the complaint and appeals decision-making process.

AIDS *Action* understands that the work of the Commission is an important step toward ensuring equal protections for health care consumers. We urge the Commissioners to clearly articulate the special health care protections needed by vulnerable populations like people living with HIV/AIDS in the final version of the Consumer Bill of Rights and Responsibilities. If AIDS *Action* can be of any additional help to the Commission, please feel free to contact me.

Sincerely,

Daniel Zingale
Executive Director

cc: Commission Members, President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry

AIDS Action council

November 14, 1997

The Honorable Alexis Herman
The Honorable Donna Shalala
Co-Chairs, President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry
Hubert H. Humphrey Building
200 Independence Avenue, SW, Suite 118-F
Washington, DC

Dear Secretaries Herman and Shalala:

AIDS *Action*, the national voice on AIDS representing 2,400 community service organizations and the people living with HIV/AIDS they help serve, has been closely monitoring the work of the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. AIDS *Action* believes that the Advisory Commission's development of a Consumer Bill of Rights and Responsibilities recognizes the need for basic consumer protections to improve quality and ensure access to care for all health care consumers, including those receiving health care through public programs like Medicaid. Significantly, the Bill of Rights is an important starting point for future action to protect the special health care needs of vulnerable, high-cost populations like people living with HIV/AIDS. AIDS *Action* argues that the only way for a Consumer Bill of Rights to be meaningful is to ensure that it is enforceable through federal law.

The Advisory Commission has made significant movement forward on a number of basic rights of particular interest to people living with HIV/AIDS. The Consumer Bill of Rights will serve as an important first step toward the enactment of enforceable federal standards ensuring that all consumers have access to quality health care. AIDS *Action* commends that Advisory Commission for the agreements already reached on key consumer rights of concern to people living with HIV/AIDS and other vulnerable populations. In particular, we support basic consumer rights to external appeals, access to specialty care, and access to information.

1875
Connecticut Ave NW
Suite 700
Washington DC
20009
Fax 202 986 1345
Tel 202 986 1300

The Advisory Commission still has to reached agreements on some issues critical to people living with HIV/AIDS, including non-discrimination, access to clinical trials, consumer responsibilities, consumer assistance/ombuds programs, and lifetime caps. AIDS *Action* urges the Advisory Commission in its deliberations to consider the barriers vulnerable populations, such as people living with HIV/AIDS, experience in the current health care environment.

Non-discrimination
The Advisory Commission has consistently articulated its intention to develop a Consumer Bill of Rights that applies to **all** health care consumers. Therefore, the scope of the non-discrimination right ought to apply to all consumers as well. People living with HIV/AIDS have faced multiple barriers to care resulting from

stigma and discrimination based on real or perceived health status. In previous discussions, the Commission has been unable to agree on the scope of a non-discrimination consumer right. AIDS *Action* contends that protections against non-discrimination should not be limited to the **provision** of covered services. Protections against non-discrimination should also apply in marketing and enrollment decisions.

Access to clinical trials

Clinical trials have been essential to improving the effectiveness of clinical treatments for numerous diseases including HIV/AIDS. AIDS *Action* encourages the Advisory Commission to protect consumer access to clinical trials. First, we urge the Advisory Commission to guarantee that participants in clinical trials have coverage for the health care services in their health plans. That is, health plans, providers, and insurers must guarantee that clinical trial participants have access to the covered services they would otherwise be eligible for outside of the clinical trial. Second, consumers must not be unreasonably limited from participating in clinical trials on the basis of the **experimental** status of the treatment. Some health plans have denied covered services to individuals on the basis that they are in clinical trials involving experimental treatment. It is unfair for consumers to be denied services for which they would have coverage because they are involved in a trial testing experimental treatments.

Consumer responsibilities

AIDS *Action* is concerned about the scope and placement of the Consumer Responsibilities chapter of the Consumer Bill of Rights. The chapter delineates clear responsibilities for consumers without acknowledging the barriers that face consumers in accessing health care. For example, consumers are often confronted with economic hardships and health conditions that prevent their ability to meet these "responsibilities." For example, both mental health conditions and drug addiction prevent many individuals from acting "responsibly" if left untreated. **Further, consumers may not receive adequate information and ongoing medical management from health plans, providers, and insurers to make truly informed choices and live up to these "responsibilities." Adherence is a joint responsibility of consumers and providers.** Also, providers have an ongoing responsibility to educate consumers about what constitutes high-risk behaviors. Therefore, AIDS *Action* strongly suggests that the Advisory Commission clarify these responsibilities to reflect the economic, social, cultural, and other barriers that face consumers.

Ombuds/consumers assistance programs

The Advisory Commission has already begun discussing the role that ombuds/consumer assistance programs could play in the health care system. AIDS *Action* urges the Advisory Commission to consider the special concerns of vulnerable populations like people living with HIV/AIDS in its future deliberations on this issue. Ombuds/consumer assistance programs could help consumers access appropriate care and ultimately avoid more costly care as a result of increased acuity. These programs could also help health plans educate consumers about plan coverage, policies, and benefits – facilitating informed health care consumers and reducing potential litigation. AIDS *Action* urges the Advisory Commission to look to the Medicare ombuds program as a successful model for the development of ombuds/consumer assistance programs for all consumers.

Lifetime caps
The Advisory has discussed mechanisms to address some of the economic barriers that prevent many vulnerable consumers from maintaining, receiving, or acquiring quality health care. Raising lifetime caps on health care coverage in the private health insurance market, for example, would help many vulnerable consumers maintain their health insurance and prevent them from becoming impoverished by their illness in order to receive public assistance. AIDS *Action* urges the Advisory Commission to make a strong statement through the Consumer Bill of Rights in support of raising or eliminating lifetime caps on health insurance coverage that inordinately affect vulnerable Americans with costly health care needs.

AIDS *Action* understands that the work of the Commission is an important step toward ensuring equal protections for health care consumers. We urge the Commissioners to clearly articulate the special health care protections needed by vulnerable populations like people living with HIV/AIDS in the final version of the Consumer Bill of Rights and Responsibilities. If AIDS *Action* can be of any additional help to the Commission, please feel free to contact me.

Sincerely,

Daniel Zingale
Executive Director

cc: Commission Members, President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry

November 18, 1997

The Honorable William J. Clinton
President of the United States of America
The White House
1600 Pennsylvania Ave., N.W.
Washington, D.C. 20500

Dear Mr. President:

Your creation of the Advisory Commission on Consumer Protection and Quality in the Health Care Industry was an important recognition of the need to identify and address quality and access problems in a dramatically changing health care system. Individuals and families increasingly fear they will not be able to get quality care when they need it. Your commitment to finding solutions to those problems is greatly appreciated.

The Advisory Commission's work is an important starting point for future action. Our organizations believe that comprehensive consumer protections are necessary and must be adopted through enforceable, federal standards. The goal of assuring that all health care consumers have access to quality care simply cannot be met without enforceable standards in place.

With the completion of its first stage of work, the Advisory Commission has reached two key conclusions. First, all members of the Advisory Commission, including representatives of the managed care and insurance industry, have recognized that many consumers face significant barriers in obtaining quality care. Second, all members of the Advisory Commission have agreed that basic protections are essential to improve quality and access and to increase confidence in the health care system. The Advisory Commission has made a critical recommendation that rights and protections apply to all consumers.

The Consumer Bill of Rights and Responsibilities in Health Care provides a framework for inclusion of additional protections for health care consumers as well as protections enabling health care providers, professionals and workers to assure quality care. We look forward to your leadership and in working with you in the effort to win adoption of an effective and enforceable consumer bill of rights.

Sincerely,

Academy of Nurse Practitioners
AIDS Action Council
American Academy of Child and Adolescent Psychiatry
American Academy of Neurology
American Academy of Pediatrics
American Academy of Physical Medicine and Rehabilitation
American Association for Psychosocial Rehabilitation

American Association of Children's Residential Centers
American Association of Neurological Surgeons
American Association of Nurse Anesthetists
American Association of Oral and Maxillofacial Surgeons
American Chiropractic Association
American College of Emergency Physicians
American College of Nurse-Midwives
American College of Physicians
American College of Surgeons
American Counseling Association
American Dental Association
American Federation of Home Health Agencies
American Federation of State, County and Municipal Employees
American Federation of Teachers
American Gastroenterological Association
American Lung Association
American Network of Community Options and Resources
American Nurses Association
American Occupational Therapy Association
American Optometric Association
American Osteopathic Association
American Physical Therapy Association
American Podiatric Medical Association
American Psychiatric Association
American Psychoanalytic Association
American Psychological Association
American Rehabilitation Association
American Society of Plastic and Reconstructive Surgeons
American Speech-Language-Hearing Association
American Therapeutic Recreation Association
American Thoracic Society
Association for Ambulatory Behavioral Health Care
Association for the Advancement of Psychology
Association of Nurses in AIDS Care
Bazelon Center for Mental Health Law
B'nai B'rith
Brain Injury Association
Center on Disability and Health
Center for Patient Advocacy
Center for Women Policy Studies
Coalition on Human Needs
College of American Pathologists
Communications Workers of America
Congress of Neurological Surgeons
Consumer Coalition for Quality Health Care
Consumer Federation of America

Corporation for the Advancement of Psychiatry
Cystic Fibrosis Foundation
D.C. Health Insurance Counseling Project
Emergency Nurses Association
Families USA
Family Service America
Four Corners AIDS Advocacy Network
Friends Committee on National Legislation
Gay and Lesbian Medical Association
Gay Men's Health Crisis
Home Health Services and Staffing Association
Human Rights Campaign
Joint Committee for Patients in Pain (American Pain Society, American Association for the Study of Headache, and the American Academy of Pain Medicine)
Justice for All
Legal Action Center
National Abortion and Reproductive Rights Action League
National Academy of Elder Law Attorneys, Inc.
National Association for the Advancement of Orthotics and Prosthetics
National Association for Rural Mental Health
National Association of Alcoholism and Drug Abuse Counselors
National Association of Area Agencies on Aging
National Association of Childbearing Centers
National Association of Children's Hospitals
National Association of Community Health Centers
National Association of People with AIDS
National Association of Protection and Advocacy Systems
National Association of Psychiatric Treatment Centers for Children
National Association of School Psychologists
National Association of Senior Companion Project Directors
National Association of Social Workers
National Black Child Development Institute
National Black Women's Health Project
National Citizen's Coalition for Nursing Home Reform
National Community Pharmacists Association
National Council of Senior Citizens
National Family Planning and Reproductive Health Association
National Farmers Union
National Health Law Program
National Mental Health Association
National Multiple Sclerosis Society
National Organization on Disability
National Osteoporosis Foundation
National Senior Citizens Law Center
National Task Force on AIDS Prevention
National Women's Law Center

Neighbor to Neighbor
NETWORK: A National Catholic Social Justice Lobby
Older Women's League
Opticians Association of America
Pituitary Tumor Network Association
Planned Parenthood Federation of America
Protestant Health Alliance
RESOLVE
Service Employees International Union
Summit Health Coalition
The Arc
The CFIDS Association of America
The Committee for Children
The National Council on Aging, Inc.
Therapeutic Communities of America
United Cerebral Palsy Association
United Church of Christ, Office for Church in Society
United Food and Commercial Workers
Women's Legal Defense Fund

November 19, 1997

NAPWA

NATIONAL ASSOCIATION OF PEOPLE WITH AIDS

The President
The White House
Washington, DC 20500

Dear Mr. President:

The National Association of People with AIDS (NAPWA) thanks you for convening an Advisory Commission on Consumer Protection and Quality in the Health Care Industry and applauds your efforts to highlight the problems of access to high quality health care for all persons in this nation.

America has struggled for decades with competing ideologies and beliefs over how best to improve the quality of health care and ensure access for everybody. In the current political environment which governs how progress toward improving our health care system must be achieved, the consensus you have sought is important. While the recommendations of the Commission fall far short of what we believe consumers need, we value them as a constructive first step. We are especially pleased that the full Commission, including representatives of managed care organizations and the employer community, have recognized that consumers face significant barriers in obtaining quality care and that basic protections are needed to ensure confidence in the health care system. NAPWA believes that these barriers are especially acute for people living with HIV and others with disabilities. Indeed, people living with HIV and others with disabilities are more likely to be without regular access to health care, they are more likely to be underserved by the health care system, and when they do not get their health care needs met, they are far more likely to experience severe adverse consequences.

As you receive the recommendations of the Advisory Commission, NAPWA urges you to exert your leadership in fighting for the development of strong, enforceable federal standards that are designed to protect our nation's most vulnerable health care consumers, including people living with HIV.

Sincerely,

A. Cornelius Baker

A. Cornelius Baker
Executive Director

1413 K Street, N.W.,
Washington D.C. 20005
Phone: (202) 898-0414
FAX: (202) 898-0435

National Organizations Responding to AIDS (NORA)
FAX MEMORANDUM

TO: NORA Coalition

FROM: NORA Executive Committee

DATE: 14 November 1997

REASON: Consumer Bill of Rights Sign-on letter

Organizations representing a broad range of coalitions have asked the Executive Committee for approval to forward their sign-on letter to the full NORA coalition. This group of organizations hopes to get as many organizations to sign onto their letter as possible. The letter urges President Clinton to adopt a Consumer Bill of Rights through enforceable federal standards. This letter is **NOT** from the NORA coalition. Please see the attached memorandum for a further explanation of the intent of this particular letter.

If you want to sign onto this letter, or have questions about it, please contact Cathy Hurwit, AFSCME, at 202-429-5006 (phone), 202-223-3413 (fax), or e-mail her at churwit@afscme.org.

From: **Cathy Hurwit [SMTP:churwit@afscme.org] <mailto:>**

Sent: Thursday, November 13, 1997 2:18 PM

To: Andersen, Amy; Lubinski, Christine; Jacobs, Jeff; ismith@aarp.org; ldriscoll@aarp.org; bcunning@aft.org; network@agc.ipc.org; smosko@aol.com; vwalker@cfids.org; lee_goldberg@cjfny.org; lisacox@compuserve.com; mitcad@consumer.org; sheaga@consumer.org; rtorres@cwa.org; awebber@erols.com; bogle@erols.com; bwlind@erols.com; mrouleau@essential.org; schlosberg@healthlaw.org; jlawnicz@naic.org; mgolde@naswdc.org; sharding@naswdc.org; collins@nmss.org; tnemore@nsclc.org; vgottlich@nsclc.org; lesterp@rtk.net; singhs@seiu.org; conoverp@ucc.org; tsteege@uuscdc.org; joanne@wldf.org

Subject: Letter to President Clinton

At a meeting yesterday, organizations representing a range of coalitions agreed to send a letter to President Clinton urging the adoption of a Consumer Bill of Rights through enforceable federal standards. The attached letter reflects comments made at a meeting this morning and subsequent comments by organizations unable to make this morning's session.

Please let me know if your organization can sign on. Please also help distribute it to interested coalition partners and organizations. The deadline is close of business on Tuesday so that we can have the letter ready for distribution at the Commission meeting on Wednesday or for a possible press event later in the week. (There will be a meeting on Monday, 11:30 a.m. at Families USA-- 1334 G Street, N.W.-to make decisions on press strategy.)

You can let me know about organizational sign-ons by e-mail (churwit@afscme.org), fax (202 223-3413) or phone (202 429-5006). Please also call me with questions or if you have problem getting the attachment.

Thanks for your help.

Cathy

The Honorable William J. Clinton
President
The White House
Washington, D.C. 20500

Dear Mr. President:

Your creation of the Advisory Commission on Consumer Protection and Quality in the Health Care Industry was an important recognition of the need to identify and address quality and access problems in a dramatically changing health care system. Individuals and families increasingly fear they will not be able to get quality care when they need it. Your commitment to finding solutions to those problems is greatly appreciated.

The Advisory Commission's work is an important starting point for future action. Our organizations believe that comprehensive consumer protections are necessary and must be adopted through enforceable, federal standards. The goal of assuring that all health care consumers have access to quality care simply cannot be met without enforceable standards in place.

With the completion of its first stage of work, the Advisory Commission has reached two key conclusions. First, all members of the Advisory Commission, including representatives of the managed care and insurance industry, have recognized that many consumers face significant barriers in obtaining quality care. Second, all members of the Advisory Commission have agreed that basic protections are essential to improve quality and access and to increase confidence in the health care system. The Advisory Commission has made a critical recommendation that rights and protections apply to all consumers.

The Consumer Bill of Rights and Responsibilities in Health Care provides a framework for inclusion of additional protections for health care consumers as well as protections enabling health care providers, professionals and workers to assure quality care. We look forward to your leadership in the effort to win adoption of an effective and enforceable Consumer Bill of Rights.

Jeff Crowley 202-898-0414
Kathy McGinley 202-785-3388

Consortium for Citizens with Disabilities

November 18, 1997

DISABILITY ORGANIZATIONS CALL FOR STRONG MANAGED CARE PROTECTIONS

Children and Adults with Disabilities Often the Worst Served by Managed Care

On the eve of the release of the "Consumer Bill of Rights" developed by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry, the Consortium for Citizens with Disabilities Health Task Force pointed out the urgency felt by people with disabilities and their families in view of the problems they currently face with managed care. * While the CCD Health Task Force sees the work of the Commission as a promising first step towards a consumer-friendly managed care industry, it also calls for decisive actions by both the Administration and Congress to ensure that children and adults with disabilities and their families have access to the health care services and supports that they need.

According to Kathleen McGinley of The Arc, a national organization on mental retardation, and co-chair of the CCD Health Task Force, "while managed care is viewed by many as a means to control health care costs while at the same time promoting good health, this has not been the reality of the disability community. Reports from consumers and advocates consistently indicate to us that access to necessary services is often either denied or severely limited by managed care organizations because of a lack of understanding of the needs of individuals with disabilities".

While the general public is apprehensive about managed care, it is consumers with disabilities and chronic illnesses who run into the worst barriers when trying to access needed services and supports through managed care. Unfortunately, it is also often these same consumers who are the least able to navigate an increasingly confounding managed care system. For them and for all others who need access to quality care, strong and enforceable federal standards and consumer protections can be the key to a productive and independent life in the community. The Commission has taken a step in the right direction by developing strong recommendations related to the provision of information to consumers so that they can make more informed choices. The Commission's support of an external appeals process is also a major step forward.

Notwithstanding these positive steps, the CCD is concerned that both the non-discrimination provisions and the provisions related to the services of an "ombudsman" to help consumers navigate the managed care maze are not as strong as they must be if consumers are to be protected. People with disabilities have for too long been discriminated against by the insurance industry. We call on the President and the Congress to take that first step and say discrimination must stop and stop now. As stated by Jeff Crowley, of the National Association of People with AIDS and co-chair of the CCD Health Task Force, "it is disappointing when a distinguished body of individuals selected by the President for their leadership in the health arena could not reach consensus on a future where the widespread discrimination experienced today by millions of people with disabilities and their families would no longer exist".

(over)

* The CCD is a Washington-based coalition of over 90 national disability organizations. The member groups of the CCD Health Task Force represent children and adults with all types of disabilities and their families, as well as advocates and providers of services and supports for these individuals.

The work of the Commission and the efforts of those Republican and Democratic Members of Congress who have heard the voices of their constituents has great potential -- if partisan politics and the unfortunate emphasis on corporate profits in the health care industry can be put aside. Ensuring that consumers -- children, adults, and families -- will have access to the health care services that they need will take great strength of character and leadership. The CCD hopes this is what will we get from both the Administration and Congress in the year to come.

CONSUMER BILL OF RIGHTS AND RESPONSIBLITIES

The "Consumer Bill of Rights" consists of the following rights and responsibilities:

(1) **Access to Accurate, Easily Understood Information** about consumers' health plans, facilities and professionals to assist them in making informed health care decisions;

(2) **Choice of Health Care Providers** that is sufficient to assure access to appropriate high quality care. This right includes assuring consumers with complex or serious medical conditions access to specialists, giving women access to qualified providers to cover routine women's health services, and providing access to continuity of care for consumers who are undergoing a course of treatment for a chronic or disabling condition;

(3) **Access to Emergency Services** when and where the need arises. This provision requires health plans to cover these services in situations where a "prudent layperson" could reasonably expect that the absence of care could place their health in serious jeopardy;

(4) **Participation in Treatment Decisions** including requiring providers to disclose any incentives, financial or otherwise -- that might influence their decisions, and prohibits "gag clauses" which restrict health care providers' ability to communicate with and advise patients about medically necessary options;

(5) **Assurance that Patients are Respected and Not Discriminated Against,** including discrimination in the delivery of health care services consistent with the benefits covered in their policy based on race, gender, ethnicity, mental or physical disability, and sexual orientation;

(6) **Confidentiality** which assures that individually identifiable medical information is not disseminated and that also provides consumers the right to review, copy and request amendments to their own medical records;

(7) **Grievance and Appeals Processes** for consumers to resolve their differences with their health plans and health care providers -- including an internal and external appeals process; and

(8) **Consumer Responsibilities** which asks consumers to take responsibility by maximizing healthy habits, becoming involved in health care decisions, carrying out agreed-upon treatment plans, reporting fraud, among others.

Background on the Commission. The President created the 34-member Advisory Commission on Consumer Protection and Quality in the Health Care Industry on March 26, 1997, charging it with "recommend[ing] such measures as may be necessary to promote and assure quality and value and protect consumers in the health care industry. " Co-Chaired by Secretary of Labor Alexis Herman and Secretary of Health and Human Services Donna Shalala. The Commission will submit their final comprehensive report on creating a quality framework, to the President on March 30, 1997.

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Todd A. Summers
11/18/97 02:04:23 PM

Record Type: Record

To: Richard Socarides/WHO/EOP

cc:
Subject: Re: POTUS Event - Quality Commission - Consumer Bill of Rights LIST

Sorry, I would add the two co-chairs of NORA (National Organizations Responding to AIDS):

Miguelina Maldonado
National Minority AIDS Council
(202) 483-6622

David Harvey
Executive Director
AIDS Policy Center for Children, Youth & Families
(202) 785-3564 x 11

System Level -
Name & Contact List -

Todd A. Summers
11/18/97 01:58:53 PM

Record Type: Record

To: Richard Socarides/WHO/EOP

cc:
Subject: Re: POTUS Event - Quality Commission - Consumer Bill of Rights LIST

I would recommend the following:

A Daniel Zingale
Executive Director
AIDS Action Council
(202) 986-1300

← Amy Anderson
(Daniel said she should come instead of him)

Cornelius Baker
Executive Director
National Assoc. of People With AIDS
(202) 898-0414 x 101

A Winnie Stachelberg
Legislative Director
Human Rights Campaign
(202) 628-4160

A Jane Silver
American Foundation for AIDS Research
(202) 331-8600

A = Priority one

Executive Summary

Consumer Bill of Rights and Responsibilities[1]

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Clinton on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights."

The Commission includes 34 members and is co-chaired by The Honorable Alexis M. Herman, Secretary of Labor, and The Honorable Donna E. Shalala, Secretary of Health and Human Services. Its members include individuals from a wide variety of backgrounds including consumers, business, labor, health care providers, health plans, state and local governments, and health care quality experts. The Commission has four Subcommittees: Consumer Rights, Protections and Responsibilities; Quality Measurement; Creating a Quality Improvement Environment; and Roles and Responsibilities of Public and Private Purchasers and Quality Oversight Organizations. The Commission and its Subcommittees meet monthly.

Following is a summary of the eight areas of consumer rights adopted by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry:

I. Information Disclosure

Consumers have the right to receive accurate, easily understood information about their health plans, facilities and professionals to assist them in making informed health care decisions.

This information should include:

- **Health plans.** Covered benefits, cost-sharing and dispute resolution mechanisms; licensure, certification and accreditation status; comparable measures of quality and consumer satisfaction; provider network composition; the procedures that govern access to specialists and emergency services; and care management information.

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[1]**This document is a preliminary draft prepared for the Advisory Commission on Consumer Protection and Quality in the Health Care Industry. Its contents have not been reviewed, discussed or approved by the Commission and should not be assumed or depicted as representing Commission views, opinions, findings, or recommendations. (October 13, 1997)**

- **Health professionals:** Education, board certification and recertification; years of practice; experience performing certain procedures; and comparable measures of quality and consumer satisfaction.

- **Health care facilities:** Experience in performing certain procedures and services; comparable measures of quality and consumer satisfaction; and procedures for resolving complaints.

II. Choice of Providers and Plans

Consumers have a right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care.

Provider Network Adequacy: All health plan networks should provide access to sufficient numbers and types of providers to assure that all covered services will be accessible without unreasonable delay -- including access to emergency services 24 hours a day and 7 days a week. When a health plan has an insufficient number or type of provider to provide a covered benefit with the appropriate degree of specialization, the plan should ensure that the consumer obtains the benefit outside the network at no greater cost than if the benefit were obtained from participating providers. Plans also should establish and maintain adequate arrangements to ensure reasonable proximity of providers to the business or personal residence of their members.

Access to Qualified Specialists for Women's Health Services. Women should be able to choose a qualified provider -- including gynecologists or certified nurse midwives -- for the provision of an adequate number of visits to cover routine women's health care services.

Access to Specialists: Consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan.

Continuity of Care: Consumers who are undergoing a course of treatment for a chronic or disabling condition (or who are in the second or third trimester of a pregnancy) at the time they involuntarily change health plans or at a time when a provider is terminated by a plan for other than cause should be able to continue seeing their current specialty providers for up to 60 days (or through completion of post-partum care) to allow for continuity of care. Providers who continue to treat such patients must accept the plan's rates as payment in full, provide all necessary information to the plan for quality assurance purposes and promptly transfer all medical records with patient authorization upon completion of the transition period.

Public and private group purchasers should, wherever feasible, offer consumers a choice of high-quality health insurance products. Small employers should be provided with greater assistance in offering their workers and their families a choice of health plans.

III. Access to Emergency Services

Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity -- including severe pain -- such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing their health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

To ensure this right:

- Health plans should educate their members about the availability, location and appropriate use of emergency and other medical services; cost-sharing provisions for emergency services; and the availability of care outside an emergency department.

- Health plans utilizing a defined network of providers should cover out-of-network emergency department screening and stabilization services without prior authorization for use consistent with the prudent layperson standard. Non-network providers and facilities should not bill patients for any charges in excess of health plans' routine payment arrangements.

- Emergency department personnel should contact a patient's primary care physician as quickly as possible to discuss follow-up and post-stabilization care and promote continuity of care.

IV. Participation in Treatment Decisions

Consumers have a right to fully participate in all decisions related to their medical care. Consumers who are unable to fully participate in treatment decisions have a right to be represented by parents, guardians, family members, or other conservators.

In order to assure consumers' right to participate in treatment decisions, physicians and other health care professionals should:

- Provide patients with sufficient information and opportunity to decide among treatment options consistent with the informed consent process. Specifically,
    - discuss all treatment options with a patient in a culturally-competent manner including the option of no treatment at all;
    - ensure that persons with disabilities have effective communications with other members of the health system in making such decisions;

- discuss all current treatments a consumer may be undergoing, including those alternative treatments that are self-administered;
- discuss all risks, benefits and consequences to treatment or nontreatment;
- give patients the opportunity to refuse treatment, to express preferences about future treatment decisions;

- Discuss the use of advance directives -- both living wills and durable powers of attorney for health care -- with patients and their designated family members;

- Abide by the decisions made by their patients and/or their designated representatives consistent with the informed consent process.

To facilitate greater communication between patients and providers, health care providers, facilities, and health plans should:

- Disclose to consumers any factors -- including method of compensation, ownership of or interest in health care facilities, or matters of conscience -- that could influence advice or treatment decisions;

- Assure that provider contracts do not contain any so-called "gag clauses" or other contractual mechanisms that unnecessarily restrict health care providers' ability to communicate with and advise patients about medically necessary treatment options;

- Protect health care professionals from penalties or retribution related to advocating on behalf of their patients.

V. Respect and Nondiscrimination

Consumers have the right to considerate, respectful care from all members of the health care industry at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Consumers must not be discriminated against in provision of health care services based on race, ethnicity, national origin, religion, sex, age, current or anticipated mental or physical disability, sexual orientation, genetic information, or source of payment.

VI. Confidentiality of Health Information

Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually-identifiable medical information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

In order to assure this right:

- With very few exceptions, individually-identifiable medical information should be disclosed for health purposes only, including the provision of health care, payment for services, health promotion, disease management, and quality assurance.

- Disclosure of individually-identifiable medical information without written consent should be permitted in very limited circumstances where there is a clear legal basis for doing so. Such reasons include but may not be limited to: medical research for which anonymous records will not suffice, investigation of health care fraud, and public health reporting. In such instances, notification of the disclosures should be made to the individual upon request.

- To the maximum feasible extent, non-identifiable health care information should be used unless the individual has consented to the disclosure of individually-identifiable information.

VII. Complaints and Appeals

All consumers have a right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them including a rigorous system of internal review and an independent system of external review.

Internal appeals systems should include:

- Timely written notification of a decision to deny, reduce or terminate services or deny payment for services. Such notification should include an explanation of the reasons for the decisions and the procedures available for appealing them.

- Resolution of all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare.

- Claim reviews should be conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved. Reviews should be conducted by individuals who were not involved in the initial decision.

- Written notification of the final determination by the plan of an internal appeal that includes information on the reason for the determination and how a consumer can appeal that decision to an external entity.

- Reasonable processes for resolving consumer complaints about such issues as waiting times, operating hours, demeanor of health care personnel, and the adequacy of facilities.

External appeals systems should:

- Be available only after consumers have exhausted all internal processes (except in cases of urgently needed care).

- Apply to any decision by a health plan to deny, reduce or terminate coverage or deny payment for services based on a determination that the treatment is either experimental or investigational in nature; or when such a decision is based on a determination that such services are not medically necessary and the amount exceeds a significant threshold or the patient's life or health is jeopardized.

- Be conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved and subject to conflict of interest prohibitions. Reviews should be conducted by individuals who were not involved in the initial decision.

- Follow a standard of review that promotes evidence-based decision making and relies on objective medical evidence.

- Resolve all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare.

VIII. Consumer Responsibilities

In a health care system that affords consumers rights and protections, it is reasonable to expect consumers to assume correlative responsibilities.

These responsibilities include:

- Lead a healthy lifestyle and, when able, assume responsibility for self care.

- Become involved in specific health care decisions.

- Honor commitments, including compliance with agreed-upon treatment regimens.

- Disclose relevant information and clearly communicate wants and needs.

- Avoid knowingly spreading disease and minimize high-risk behavior.

- Use their health plan's internal complaint and appeal processes to address concerns that may arise.

- Recognize the reality of risks and limits of the science of medical care and the fallibility of the health care professional.

- Be aware of a health care provider's obligation to be reasonably efficient and equitable in providing care to other patients and the community.

- Become knowledgeable about their health plan coverage and health plan options (when available) including all covered benefits, limitations and exclusions, rules regarding use of network providers, coverage and referral rules, appropriate processes to secure additional information, and the process to appeal coverage decisions.

- Pay all appropriate bills or make arrangements to have them paid.

- Abide by administrative and operational procedures of health plans, health care providers and government health benefit programs.

- Report wrongdoing and fraud to appropriate resources or legal authorities.

THE WHITE HOUSE
WASHINGTON

Sophia

HIV - Info Disclosure
- covered benefits
- formulary + related issues
  (prior authorization)
  add'l hurdles for combo
  price limits or cutoffs
  how are they updated/available

health prof's
AIDS experience

Provider Choice
Access to HIV specialist
w/in specialty fields, want to know about HIV experience

Part in Tx Decisions

Confidentiality
Stepped Capitation means more disclosure

THE WHITE HOUSE
WASHINGTON

Complaints
Timeliness

EXECUTIVE SUMMARY

Consumer Bill of Rights and Responsibilities

The Advisory Commission on Consumer Protection and Quality in the Health Care Industry was appointed by President Clinton on March 26, 1997, to "advise the President on changes occurring in the health care system and recommend measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of its work, the President asked the Commission to draft a "consumer bill of rights."

The Commission includes 34 members and is co-chaired by The Honorable Alexis M. Herman, Secretary of Labor, and The Honorable Donna E. Shalala, Secretary of Health and Human Services. Its members include individuals from a wide variety of backgrounds including consumers, business, labor, health care providers, health plans, State and local governments, and health care quality experts. The Commission has four Subcommittees: Consumer Rights, Protections, and Responsibilities; Quality Measurement; Creating a Quality Improvement Environment; and Roles and Responsibilities of Public and Private Purchasers and Quality Oversight Organizations. The Commission and its Subcommittees meet monthly.

Following is a summary of the eight areas of consumer rights adopted by the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry:

I. Information Disclosure

Consumers have the right to receive accurate, easily understood information about their health plans, facilities, and professionals to assist them in making informed health care decisions.

This information should include:

- **Health plans.** Covered benefits, cost-sharing, and procedures for resolving complaints; licensure, certification, and accreditation status; comparable measures of quality and consumer satisfaction; provider network composition; the procedures that govern access to specialists and emergency services; and care management information.

- **Health professionals:** Education, board certification and recertification; years of practice; experience performing certain procedures; and comparable measures of quality and consumer satisfaction.

- **Health care facilities:** Experience in performing certain procedures and services; accreditation status; comparable measures of quality and worker and consumer satisfaction; procedures for resolving complaints; and community benefits provided.

II. Choice of Providers and Plans

Consumers have the right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care.

To assure such choice, health plans should provide the following:

Provider Network Adequacy: All health plan networks should provide access to sufficient numbers and types of providers to assure that all covered services will be accessible without unreasonable delay—including access to emergency services 24 hours a day and 7 days a week. If a health plan has an insufficient number or type of providers to provide a covered benefit with the appropriate degree of specialization, the plan should ensure that the consumer obtains the benefit outside the network at no greater cost than if the benefit were obtained from participating providers. Plans also should establish and maintain adequate arrangements to ensure reasonable proximity of providers to the business or personal residence of their members.

Access to Qualified Specialists for Women's Health Services: Women should be able to choose a qualified provider—including gynecologists and other qualified health care providers offered by a plan—for the provision of covered care necessary to provide routine preventative women's health care services.

Access to Specialists: Consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan.

Transitional Care: Consumers who are undergoing a course of treatment for a chronic or disabling condition (or who are in the second or third trimester of a pregnancy) at the time they involuntarily change health plans or at a time when a provider is terminated by a plan for other than cause should be able to continue seeing their current specialty providers for up to 90 days (or through completion of post-partum care) to allow for transition of care. Providers who continue to treat such patients must accept the plan's rates as payment in full, provide all necessary information to the plan for quality assurance purposes, and promptly transfer all medical records with patient authorization during the transition period.

Public and private group purchasers should, wherever feasible, offer consumers a choice of high-quality health insurance products. Small employers should be provided with greater assistance in offering their workers and their families a choice of health plans and products.

III. Access to Emergency Services

Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

To ensure this right:

- Health plans should educate their members about the availability, location, and appropriate use of emergency and other medical services; cost-sharing provisions for emergency services; and the availability of care outside an emergency department.

- Health plans using a defined network of providers should cover emergency department screening and stabilization services both in network or out of network without prior authorization for use consistent with the prudent layperson standard. Non-network providers and facilities should not bill patients for any charges in excess of health plans' routine payment arrangements.

- Emergency department personnel should contact a patient's primary care physician or health plan, as appropriate, as quickly as possible to discuss follow up and post-stabilization care and promote continuity of care.

IV. Participation in Treatment Decisions

Consumers have the right and responsibility to fully participate in all decisions related to their medical care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.

In order to assure consumers' right and ability to participate in treatment decisions, physicians and other health care professionals should:

- Provide patients with sufficient information and opportunity to decide among treatment options consistent with the informed consent process. Specifically,

    - Discuss all treatment options with a patient in a culturally competent manner, including the option of no treatment at all.

    - Ensure that persons with disabilities have effective communications with members of the health system in making such decisions.

- Discuss all current treatments a consumer may be undergoing, including those alternative treatments that are self-administered.
- Discuss all risks, benefits, and consequences to treatment or nontreatment.
- Give patients the opportunity to refuse treatment and to express preferences about future treatment decisions.

- Discuss the use of advance directives—both living wills and durable powers of attorney for health care—with patients and their designated family members.
- Abide by the decisions made by their patients and/or their designated representatives consistent with the informed consent process.

To facilitate greater communication between patients and providers, health care providers, facilities, and plans should:

- Disclose to consumers any factors—including method of compensation, ownership of or interest in health care facilities, or matters of conscience—that they know or should have known could influence advice or treatment decisions.
- Assure that provider contracts do not contain any so-called "gag clauses" or other contractual mechanisms that restrict health care providers' ability to communicate with and advise patients about medically necessary treatment options.
- Be prohibited from penalizing or seeking retribution against health care professionals or other health workers for advocating on behalf of their patients.

V. Respect and Nondiscrimination

Consumers have the right to considerate, respectful care from all members of the health care industry at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Consumers must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Consumers who are eligible for coverage under the terms and conditions of a health plan or program must not be discriminated against in marketing and enrollment practices based

on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

VI. Confidentiality of Health Information

Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

In order to assure this right:

- With very few exceptions, individually identifiable health care information should be disclosed for health purposes only, including the provision of health care, payment for services, peer review, health promotion, disease management, and quality assurance.

- Disclosure of individually identifiable medical information without written consent should be permitted in very limited circumstances where there is a clear legal basis for doing so. Such reasons include: medical research for which an institutional review board has determined anonymous records will not suffice, investigation of health care fraud, and public health reporting. In such instances, notification of the disclosures should be made to the individual upon request.

- To the maximum feasible extent in all situations, non-identifiable health care information should be used unless the individual has consented to the disclosure of individually identifiable information. When disclosure is required, no greater amount of information should be disclosed than is necessary to achieve the specific purpose of the disclosure.

- Health providers, facilities, and plans should develop procedures to ensure that when sensitive services (e.g., mental health, substance abuse, reproductive services, or treatment of sexually transmitted diseases) are involved, standard administrative techniques do not inadvertently disclose information to individuals other than the patient.

VII. Complaints and Appeals

All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.

Internal appeals systems should include:

- Timely written notification of a decision to deny, reduce, or terminate services or deny payment for services. Such notification should include an explanation of the reasons for the decisions and the procedures available for appealing them.

- Resolution of all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare (i.e., 72 hours).

- A claim review process conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved. Reviews should be conducted by individuals who were not involved in the initial decision.

- Written notification of the final determination by the plan of an internal appeal that includes information on the reason for the determination and how a consumer can appeal that decision to an external entity.

- Reasonable processes for resolving consumer complaints about such issues as waiting times, operating hours, the demeanor of health care personnel, and the adequacy of facilities.

External appeals systems should:

- Be available only after consumers have exhausted all internal processes (except in cases of urgently needed care).

- Apply to any decision by a health plan to deny, reduce, or terminate coverage or deny payment for services based on a determination that the treatment is either experimental or investigational in nature; apply when such a decision is based on a determination that such services are not medically necessary and the amount exceeds a significant threshold or the patient's life or health is jeopardized.

- Be conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved and subject to conflict of interest prohibitions. Reviews should be conducted by individuals who were not involved in the initial decision.

- Follow a standard of review that promotes evidence-based decisionmaking and relies on objective medical evidence.

- Resolve all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare (i.e., 72 hours).

VIII. Consumer Responsibilities

Greater individual involvement by consumers in their health care provides consumers with more control over the outcome of that care. The Commission encourages consumers to strive to meet as many of the following responsibilities as possible:

- Take responsibility for maximizing healthy habits, such as exercising, not smoking, and eating a healthy diet.

- Become involved in specific health care decisions.

- Work with health care providers in developing and carrying out agreed-upon treatment plans.

- Disclose relevant information and clearly communicate wants and needs.

- Use the health plan's internal complaint and appeal processes to address concerns that may arise.

- Recognize the reality of risks and limits of the science of medical care and the human fallibility of the health care professional.

- Be aware of a health care provider's obligation to be reasonably efficient and equitable in providing care to other patients and the community.

- Become knowledgeable about his or her health plan coverage and health plan options (when available) including all covered benefits, limitations, and exclusions, rules regarding use of network providers, coverage and referral rules, appropriate processes to secure additional information, and the process to appeal coverage decisions.

- Make a good-faith effort to meet financial obligations.

- Abide by administrative and operational procedures of health plans, health care providers, and Government health benefit programs.

- Report wrongdoing and fraud to appropriate resources or legal authorities.

PREAMBLE

A Consumer Bill of Rights and Responsibilities

American consumers and their families are experiencing an historic transition of the U.S. system of health care financing and delivery. In establishing the Advisory Commission on Consumer Protection and Quality in the Health Care Industry, President Clinton asked that it advise him "on changes occurring in the health care system and recommend such measures as may be necessary to promote and assure health care quality and value, and protect consumers and workers in the health care system." As part of that effort, the President has asked the Commission to draft a Consumer Bill of Rights and Responsibilities.

This Commission includes 34 members from a wide variety of backgrounds including consumers, business, labor, health care providers, health plans[1], State and local governments, and health care quality experts. We hope our diversity of interests and backgrounds will make our recommendations more valuable to those who consider them.

This is an appropriate time to reexamine and reconsider the methods by which our Nation and the health care industry establish and protect the rights and identify the responsibilities of those people who use the health care system. The Commission believes it is essential to preserve those elements of the emerging system that have a positive impact on the quality of care as well as the cost and availability of health insurance coverage.

Development of a Consumer Bill of Rights and Responsibilities is an important step forward for all those involved in the health care system. Consumers, health care professionals, administrators of health care facilities, and those who operate health plans will benefit from a clear set of unifying standards. The Consumer Bill of Rights and Responsibilities can help to establish a stronger relationship of trust among consumers, health care professionals, health care institutions, and health plans by helping to sort out the shared responsibilities of each of these participants in a system that promotes quality improvement.

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[1]The term "health plans" is used throughout this report and refers broadly to indemnity insurers, managed care organizations (including health maintenance organizations and preferred provider organizations), self-funded employer-sponsored plans, Taft-Hartley trusts, church plans, association plans, State and local government employee programs, and public insurance programs (i.e., Medicare and Medicaid).

The work of this Commission builds on the efforts of many others. The Commission reviewed dozens of proposals prepared and released by a variety of organizations[2] that have addressed the rights, responsibilities, and protection of consumers. We have heard public testimony from dozens of individuals and organizations. We are grateful for their contributions.

The Consumer Bill of Rights and Responsibilities charts a course for the continued enhancement of health systems and processes that serve to protect consumers and assure quality. While the rights and responsibilities included in this report are intended to apply to all consumers and participants in the health care system, the Commission recognizes that the strength of these protections will grow over time as the capabilities of the health care industry become more sophisticated. Certain portions of the industry will require additional time to make these adjustments, but the Commission intends that the bulk of its recommendations be put in place within the next 3 years.

The Consumer Bill of Rights and Responsibilities was first drafted by the Subcommittee on Consumer Rights, Protections, and Responsibilities. The Subcommittee met in open session on seven separate occasions and the Commission met six times during that same time period. The Subcommittee considered background papers on each topic, heard public testimony on most topics, and considered two or three drafts of each chapter. At each point in that process, the Subcommittee briefed the full Commission on its work and received feedback on those issues. The Commission also has considered draft chapters and revised drafts reflecting the input of its members. Throughout this process, the Subcommittee and the Commission have operated on a consensus basis that has allowed any member to place an issue before the respective body for consideration. The list of issues was refined to reflect the discussions of the Subcommittee and the Commission. The final product reflects the areas of overall agreement expressed by Commission members.

Objectives of a Consumer Bill of Rights and Responsibilities

The Consumer Bill of Rights and Responsibilities is intended to accomplish five major goals.

First, to strengthen consumer confidence by assuring the health care system is fair and responsive to consumers' needs, provides consumers with credible and effective mechanisms to address their concerns, and encourages consumers to take an active role in improving and assuring their health.

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[2]The Commission examined proposals by organizations including: the American Association of Health Plans, the American Association of Retired Persons, the American Hospital Association, the American Medical Association, Citizen Action, the Campaign for Health Security, Families USA, the Health Insurance Association of America, the Health Policy Tracking Service, Kaiser Permanente, the Midwest Bioethics Center, the National Association of Insurance Commissioners, the National Committee on Quality Assurance, the National Health Council, the Public Policy and Education Fund of New York, the Service Employees International Union, the Utilization Review Accreditation Committee, and many others.

Second, to reaffirm the importance of a strong relationship between patients and their health care professionals.

Third, to reaffirm the critical role consumers play in safeguarding their own health by establishing both rights and responsibilities for all participants in improving health status.

Guiding Principles for the Consumer Bill of Rights and Responsibilities

The work of the Commission was guided by the following principles:

All consumers are created equal. The work of this Commission in establishing a Bill of Rights and Responsibilities must apply to all consumers. This includes all beneficiaries of such public programs as Medicare, Medicaid, the Department of Veterans Affairs, and the Department of Defense, as well as Federal, State and local government employees. It also includes all those who have private insurance, including those who purchase their own insurance, those who work for companies that have self-funded health plans, and those who work for companies that purchase insurance for their employees and dependents. And, finally, to the extent possible, these rights should be accorded to those who have no health insurance but use the health care system.

Quality comes first. The first question we asked ourselves in each circumstance was: Will this improve the quality of care and of the system that delivers that care? Sometimes this led us to reject policy options that we believe could hinder the progress our Nation has made toward a health care system that is focused on improving quality through accountable organized systems.

Preserve what works. There are elements of managed care and of indemnity coverage that must be changed to protect the rights of consumers. But there also are elements of each system that have improved quality and expanded access. We have tried to make sure that we preserve what works while we address areas that can and should be improved.

Costs matter. The Commission has sought to balance the need for stronger consumer rights with the need to keep coverage affordable, but we recognize that, in some circumstances, these rights may create additional costs for employers; health insurers and plans; Federal, State, and local governments; and consumers. We also recognize that ultimately consumers bear these costs in the form of lower wages, higher prices, higher taxes, or reduced benefits in other areas. The Commission has attempted to weigh these factors carefully and support recommendations that may prompt additional spending in cases where such spending may represent an investment in higher quality health care and better health outcomes.

Goals for Consumer Protection in a Quality-Focused Health Care System

A Consumer Bill of Rights and Responsibilities is, by its nature, a snapshot of what is needed

at a particular time. The rights enumerated in this report are intended to move the health care system in a direction that is consistent with a system of health care delivery that is focused on obtaining the highest quality and best outcome for consumers and their families. In that light, the Commission has identified a series of goals for the continued reform of the American health care system that will maximize consumer rights in a system that focuses on quality.

Health coverage is the best consumer protection. A health care system that leaves more than 41 million Americans without health coverage cannot adequately protect the rights of consumers and their families. The fact that so many Americans live day in and day out without the security that health coverage provides is intolerable. Recent trends reported by the U.S. Census Bureau that the number of uninsured Americans rose by one million between 1996 and 1997 are cause for great concern. Moreover, the continued existence of a large group of Americans without health insurance increases the costs paid by those who have insurance as uncovered expenses are shifted to other purchasers. Efforts by Federal and State governments to expand the number of children who are insured are encouraging and should be strengthened. Similar efforts should be extended to other segments of the population so that all Americans are covered.

Consumers faced with catastrophic illness require assistance. Each year, an estimated 1,500 to 2,500 Americans lose their private health insurance coverage because their medical expenses exceed a lifetime limit included in their health insurance policy. Many of these consumers must exhaust their family savings before becoming eligible for Medicaid or other forms of public assistance. This creates a tremendous hardship on these individuals and their families. Employers, health plans, and others should consider taking steps to ease this burden by (1) eliminating or increasing lifetime limits, (2) expanding the use of high-risk pools to provide immediate coverage at the time consumers reach a lifetime limit, or (3) offering supplemental coverage for workers who wish to increase their limits.

Coverage must be made affordable for all consumers, employers, and other purchasers. The recent moderation in health care costs is promising and has been a contributing factor in the slowing of insurance coverage losses. Employers, health plans, and Federal and State governments should be applauded for their efforts to make coverage more affordable for more Americans. Recent projections for 1998 are less favorable. History makes clear that we cannot assume that costs will remain under control without continued cost containment.

Vulnerable groups require special attention. Many consumers are, for reasons beyond their control, more vulnerable than others to losing their coverage or experiencing significant gaps in their coverage. Individuals with mental or physical disabilities, low-income individuals, children, non-English-speaking consumers, and others require considerable attention by decisionmakers at all levels of the system. Enactment of the Americans with Disabilities Act of 1990, the Health Insurance Portability and Accountability Act of 1996, and the Mental Health Parity Act of 1996 were important steps to protect these consumers. Further steps can and should be taken.

Small purchasers need assistance. The owners of small businesses, the self-employed, and those who purchase insurance in the individual market continue to have great difficulty finding and maintaining affordable health care coverage. For a variety of reasons, insurance premiums are higher for small firms relative to the benefits they are able to purchase, and some small firms are unable to purchase insurance at all. In its final report, the Commission intends to offer several recommendations to help ameliorate some of these effects, including voluntary approaches for expanding insurance pools and for adjusting payment systems to reflect the greater risk inherent in small group and individual markets.

Consumer participation in clinical research. The national investment in clinical research has led to breakthrough advances in diagnosis, prevention, and treatment of illness and disability that have lengthened and improved the quality of life for millions of consumers while also achieving significant cost-savings to the health care industry. Consumer participation in clinical research through their inclusion in clinical trials is vitally important not only to continued advancement and innovation in medical care but to the often life-threatening nature of the conditions affecting such consumers. The Commission is encouraged by the ongoing efforts by researchers, health plans, employers, and others to resolve impediments to consumer participation in clinical trials and urges participants to reach agreement on an appropriate sharing of costs and responsibilities related to such trials.

CHAPTER ONE

Information Disclosure

STATEMENT OF THE RIGHT

Consumers have the right to receive accurate, easily understood information about their health plans, facilities, and professionals to assist them in making informed health care decisions.

This information should include:

- **Health plans.** Covered benefits, cost-sharing, and procedures for resolving complaints; licensure, certification, and accreditation status; comparable measures of quality and consumer satisfaction; provider network composition; the procedures that govern access to specialists and emergency services; and care management information.

- **Health professionals:** Education, board certification and recertification; years of practice; experience performing certain procedures; and comparable measures of quality and consumer satisfaction.

- **Health care facilities:** Experience in performing certain procedures and services; accreditation status; comparable measures of quality and worker and consumer satisfaction; procedures for resolving complaints; and community benefits provided.

RATIONALE

Value-based purchasing allows consumers to obtain greater value for their health care dollar by seeking higher quality care at the best price. To do this, consumers need accurate, reliable information that will allow them to assess differences in the quality and cost of health benefits plans, the health care providers who treat them, and the facilities and institutions that house them. Active and informed decisionmaking by consumers will improve the performance of the health care system, as providers seek to enhance their quality and reduce their costs in order to be more attractive to value-seeking consumers.

A more basic reason for providing consumers with information is an ethical one. Health plans, facilities, and professionals have an ethical obligation to inform consumers about how their actions can affect the consumer's life and health. Medical ethicists ground this obligation in the principle of respect for individual autonomy and individuals' right to make choices about how they receive medical care (Beauchamp and Childress, 1994).

This chapter provides a description of the types of information on health plans, health professionals, and health care facilities that should be made available to consumers either routinely or upon request. The Commission recognizes that much work remains to be done if all this information is to be readily available and understandable to consumers, specifically:

- *Detailed explanation is needed for certain types of information.* Some types of information are straightforward and require no further definition (e.g., the names, board certification status, and geographic location of primary care providers in a plan's network). Other types of information would benefit from the development of more detailed explanation, such as the care management information on clinical protocols, practice guidelines, and pre-authorization and utilization review standards and procedures.

- *Standardized measures are needed for comparative purposes.* For the information intended to support consumer decisions regarding the choice of a health benefits plan, or choice of an individual provider or facility, standardized definitions will be needed to allow for "apples to apples" comparisons. Examples included compliance with evidence-based guidelines and a health care professional's experience in performing certain procedures (adjusted for case mix and severity).

- *Ongoing development and promulgation of standardized measurement sets and instruments are needed for assessing satisfaction and quality.* The Commission believes that some of the most important types of information a consumer has a right to receive fall into the categories of consumer satisfaction ratings and clinical quality performance measures for health plans, health care professionals, and facilities. For all consumers to exercise this right, processes must be put in place to create standardized performance measures. In its final report, the Commission intends to address how such a process might be established so as to build on existing efforts, encourage ongoing innovation in quality measurement, and provide the best possible information to consumers at any given time to encourage quality improvement through market-based decisions.

- *Useful and appropriate reporting formats and processes are needed for consumers.* Although the Commission believes that consumers should have access to pertinent information, it recognizes that caution must be taken to provide information to consumers in useful formats (e.g., summary and detailed reports; printed copy, and Internet), at appropriate times (i.e., decision points), with assistance for vulnerable groups (i.e., those who are hearing impaired or non-English speaking). These issues also will be addressed in the Commission's final report.

Consumers should be able to obtain other information upon request as outlined below. Plans, providers, and facilities should inform consumers that such information is available and describe how it can be obtained.

Health Plan[1] Information

Many consumers face a choice of health plans such as an indemnity plan, an HMO, a point-of-service plan, or a preferred provider organization. Consumers' choice of a health plan has a significant impact on consumers' ability to make other choices about facilities, health professionals, and treatment options. Even in cases where consumers do not have a choice of plans, they require information on the plan in which they are enrolled to use the available services effectively.

To the extent that a right to information creates disclosure requirements for health plans, these requirements should apply equally to all types of plans (including indemnity, HMO, PPO, and POS) regardless of sponsor (e.g., such Government programs as CHAMPUS, VA, FEHBP, Medicare, and Medicaid and private plans including fully funded, partially self-funded, or fully self-funded plans). If the specific information required for disclosure does not exist, or is unavailable, the consumer should be informed.

The primary responsibility of providing consumers with health plan information falls upon the plans themselves. In the case of self-insured plans, this responsibility will rest with the plan sponsor unless it is delegated or contracted to a third-party administrator.

Within the category of health plan information, one can discern four principal subcategories of information: 1) benefits, cost-sharing, and dispute resolution; 2) health plan characteristics and performance information; 3) network characteristics; and 4) care management information.

A. **Benefits, Cost Sharing, and Dispute Resolution.** Consumers should receive the following information about a health benefits plan:

- A general summary of all covered benefits, including:
  - General limits on coverage, including any annual or lifetime limits, as well as limits for specific conditions.
  - Whether preventative services are covered.
  - Whether a drug formulary is used and, if so, how decisions are made pertaining to inclusion of drugs, particularly new drugs (including a process to consider exceptions).

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[1]The term "health plan" is used throughout this report and refers broadly to indemnity insurers, managed care organizations (including health maintenance organizations and preferred provider organizations), self-funded employer-sponsored plans, Taft-Hartley trusts, church plans, association plans, State and local government employee programs, and public insurance programs (i.e., Medicare and Medicaid).

- How drugs, devices, and procedures are deemed experimental.

- Enrollee cost-sharing, including employee or beneficiary premium contributions, deductibles, copayments, and co-insurance.

- Type and extent of dispute resolution procedures available in the event of a dispute.

B. **Health Plan Characteristics and Performance Information.** Consumers joining or considering whether or not to join a health plan should receive information about:

- State licensure status, Federal certification, and private accreditation status (including publicly available reports).

- Consumer satisfaction measures.

- Clinical quality performance measures.

- Service performance measures (e.g., waiting time to obtain an appointment with primary care providers and specialists).

- Disenrollment rates (adjusted for involuntary disenrollment and other relevant factors).

Additional information that should be made available *upon request* includes:

- Number of years in existence.

- Corporate form of the plan (i.e., public or private; non-profit or for-profit ownership and management).

- Whether the plan meets requirements (State and Federal) for fiscal solvency.

- Whether the plan meets standards (State, Federal, and private accreditation) that assure confidentiality of medical records and orderly transfer to care givers.

C. **Network Characteristics.** It is important to provide consumers with information about the characteristics of the network and the procedures that govern its use. Consumers should receive:

- Aggregate information on the numbers, types, board certification status, and geographic distribution of primary care providers and specialists.

- Detailed listings of the names, board certification status, and geographic location of all contracting primary care providers, whether they are accepting new patients, language(s)

spoken and interpreter services available, and whether facilities are accessible to people with disabilities.

- Provider compensation methods, including base payment (e.g., capitation, salary, fee schedule) and additional financial incentives (e.g., bonus, withholds, etc.).

- Rules regarding coverage of out-of-network services, and applicable rates of cost-sharing.

- Information about circumstances under which primary care referral is required to access specialty care.

- Information about what options exist for 24-hour coverage and whether enrollees have access to urgent care centers.

Additional information that should be made available *upon request* includes:

- Detailed list of names, board certification status, and geographic location of all contracting specialists and specialty care centers, whether they are accepting new patients, language(s) spoken, interpreter services available, and whether facilities are accessible to people with disabilities.

- Detailed list of names, accreditation status, and geographic location of hospitals, home health agencies, rehabilitation and long-term care facilities, and whether they are accepting new patients, languages spoken, interpreter services available, and whether they are accessible to people with disabilities.

D. Care Management Information. Information in this category that should be available *upon request* includes:

- Preauthorization and utilization review procedures followed.

- Use of clinical protocols, practice guidelines, and utilization review standards pertinent to a patient's clinical circumstances.

- Whether the plan has special disease management programs or programs for persons with disabilities. (This information should indicate whether these programs are voluntary or mandatory or if a significant benefit differential results.)

- Whether a specific prescription drug is included in a formulary and procedures for considering requests for patient-specific waivers.

- Qualifications of reviewers at the primary and appeals levels.

Health Professional Information

All consumers should receive information on:

- Whether the health professional's ownership or affiliation arrangement with a provider group or institution would make it more likely that a consumer would be referred to particular specialists or facility or receive a particular service.

- How the provider is compensated, including base payment method (e.g., capitation, salary, fee schedule) and types of additional financial incentives (e.g., bonus, withholds).

Consumers should receive *upon request* the following information on health professionals:

- Education, board certification, and recertification status.

- Names of hospitals where physicians have admitting privileges.

- Years of practice as a physician and as a specialist if so identified.

- Experience with performing certain medical or surgical procedures (e.g., volume of care/services delivered), adjusted for case mix and severity.

- Consumer satisfaction measures.

- Clinical quality performance measures.

- Service performance measures.

- Accreditation status (if applicable).

- Corporate form of the practice (i.e., public or private, non-profit or for-profit, ownership and management, sole proprietorship or group practice).

- The availability of translation or interpretation services for non-English speakers and people with communication disabilities.

- Any cancellation, suspension, or exclusion from participation in Federal programs or sanctions from Federal agencies; any suspension, revocation, or voluntary surrender of medical licensure, Federal controlled substance license, or hospital privileges.

Health Care Facility Information

Consumers should receive the following information from a health care facility:

- Corporate form of the facility (i.e., public or private; non-profit or for-profit, ownership and management, affiliation with other corporate entities).
- Accreditation status.
- Whether specialty programs meet guidelines established by specialty societies or other appropriate bodies (e.g., whether a cancer treatment center has been approved by the American College of Surgeons, the Association of Community Cancer Centers, or the National Cancer Institute).
- The volume of certain procedures performed at each facility.
- Consumer satisfaction measures.
- Clinical quality performance measures.
- Service performance measures.
- Procedures for registering a complaint and achieving resolution of that complaint.
- The availability of translation or interpretation services for non-English speakers and people with communication disabilities.
- Numbers and credentials of providers of direct patient care (e.g., registered nurses, other licensed providers, and other care givers).
- Whether the facility's affiliation with a provider network would make it more likely that a consumer would be referred to health professionals or other organizations in that network.
- Whether the facility has been excluded from any Federal health programs (i.e., Medicare or Medicaid).

IMPLICATIONS OF THE RIGHT

Obtaining the information listed above and making it available to consumers will not, by itself, equip consumers with the knowledge and abilities required to act on this information. Discussed below are some basic considerations in making this information useful to consumers and the implications of this for key segments of the health care industry.

Information Should Be Useful to Consumers and Cost-Effective to Obtain. Edgman-Levitan and Cleary (1996) have documented that consumers are able to evaluate critically information about quality. However, research on how consumers use information to make decisions suggests that too much information can be overwhelming. In its 1988 assessment of methods for communicating the quality of medical care to consumers, the Office of Technology Assessment's Expert Advisory Panel concluded that "limiting information to only a few indicators of quality will probably be necessary [because] people can consider only a few items at any one time. Information is processed as a unit or chunk—a person's processing capacity has been estimated as being anywhere from four to seven chunks (OTA, 1988)." Ongoing research must be conducted to determine what is the most effective subset of information that consumers can use. Finally, while consumers clearly have a right to information, it must be understood that there are costs associated with collecting and distributing it. While providing information to consumers generates significant benefits for both the consumers and the health system as a whole, it is not necessarily inexpensive. Recognizing these costs, however, is not an argument for a "bare bones" approach to information disclosure. The failure to provide information also has costs. Well-informed consumers are the bedrock of an efficiently operating market. Without meaningful information, consumers are more likely to make choices that can result in less than optimal outcomes for themselves and there is less incentive for participants to strive for excellence. The challenge is to develop coordinated approaches to information collection and dissemination that will provide consumers the information they need to make decisions without imposing severe burdens on plans and providers.

Investments in Clinical Information Systems and Workforce Education and Training Will Be Needed. Greater investment in automated information systems will be necessary for health plans and providers to satisfy these information disclosure requirements, especially ones pertaining to product, facility, and provider performance and quality. The Commission is currently assessing barriers or impediments to investment in clinical information systems (e.g., inadequate data collection standards; confidentiality concerns; magnitude of capital investments required) and plans to speak to this issue in its final report. Responding to these increased information demands also has implications for the training and education of the health care workforce. There will be greater demand by health care organizations for individuals with particular technical and analytic skills (e.g., computer programming, engineering, data auditing, and statistics). Ongoing training and continuing education programs for practitioners and other workers whose work involves recording, compiling, or manipulating clinical and administrative data will also be needed to assure the completeness and accuracy of data and adherence to confidentiality safeguards.

REFERENCES

Beauchamp TL, Childress JF. Principles of biomedical ethics (New York): Oxford University Press; 1994.

Edgeman-Levitan S, Cleary S and P. What information do consumers want and need: What do we know about how they judge quality and accountability? In: Jones SB, Lewin ME, editors, Improving the Medicare market: Adding choice and protections. Washington, DC: National Academy Press; 1996.

Office of Technology Assessment. The quality of medical care: Information for consumers. No. OTA-H-386. Washington, DC; 1988.

Sofaer S. How will we know if we got it right? Aims, benefits and risks of consumer information initiatives. The Joint Commission Journal on Quality Improvement 23(5); May 1997;258-264.

CHAPTER TWO

Choice of Providers and Plans

STATEMENT OF THE RIGHT

Consumers have the right to a choice of health care providers that is sufficient to assure access to appropriate high-quality health care.

To assure such choice, health plans should provide the following:

Provider Network Adequacy: All health plan networks should provide access to sufficient numbers and types of providers to assure that all covered services will be accessible without unreasonable delay—including access to emergency services 24 hours a day and 7 days a week. If a health plan has an insufficient number or type of providers to provide a covered benefit with the appropriate degree of specialization, the plan should ensure that the consumer obtains the benefit outside the network at no greater cost than if the benefit were obtained from participating providers. Plans also should establish and maintain adequate arrangements to ensure reasonable proximity of providers to the business or personal residence of their members.

Access to Qualified Specialists for Women's Health Services: Women should be able to choose a qualified provider—including gynecologists and other qualified health care providers offered by a plan—for the provision of covered care necessary to provide routine preventative women's health care services.

Access to Specialists: Consumers with complex or serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan.

Transitional Care: Consumers who are undergoing a course of treatment for a chronic or disabling condition (or who are in the second or third trimester of a pregnancy) at the time they involuntarily change health plans or at a time when a provider is terminated by a plan for other than cause should be able to continue seeing their current specialty providers for up to 90 days (or through completion of post-partum care) to allow for transition of care. Providers who continue to treat such patients must accept the plan's rates as payment in full, provide all necessary information to the plan for quality assurance purposes, and promptly transfer all medical records with patient authorization during the transition period.

Public and private group purchasers should, wherever feasible, offer consumers a choice of high-quality health insurance products. Small employers should be provided with greater assistance in offering their workers and their families a choice of health plans and products.

RATIONALE

The ability of consumers to exercise choice in the health care marketplace is associated with several desirable characteristics of a health care system.

- First, choice is associated with increased consumer satisfaction. In a survey of consumers receiving health care in both indemnity and managed care plans, individuals with a choice of health products report greater satisfaction with their plan and tend to rate both their health insurance product and their individual physicians of higher quality (Davis and Schoen, 1997).

- Second, the ability of consumers to choose among competing products is a hallmark of a healthy marketplace. Individual consumers are responsible for 34 percent of all direct expenditures for health care in the United States (Cowan et al., 1996). As the science of measuring and generating accurate and valid information on the quality of health plans, providers and facilities advances, consumers can wield their purchasing power to create incentives in the marketplace for improvements in health care quality.

- Third, consumers who have a role in the selection of their caregivers are likely to have greater confidence in those practitioners and are, therefore, more likely to seek appropriate care in a more timely fashion and follow agreed-upon care regimens.

- Fourth, having a choice of providers allows consumers to take action to preserve continuity of care within the health care system by selecting products and providers that allow them to continue provider relationships when continuity of care is especially important (e.g., prenatal care, care of individuals with complex chronic or disabling conditions).

Thus, a health care marketplace that promotes satisfied consumers, continuity of care, and continuous improvements in quality requires that an array of choices be available to consumers. Without consumers' ability to have and exercise choice, greater activities may need to be undertaken by group purchasers and regulators to ensure that the health care marketplace responds appropriately to consumers' health care needs.

Consumer Choice of Health Plans or Products

During the last decade, there has been a marked increase in the number and types of health insurance products available in most geographic markets. Prior to the widespread development of managed care plans, most Americans had limited choice of health insurance products.

Indemnity products dominated the market with HMO and PPO products available primarily in certain metropolitan areas. The past 10 years have seen a significant increase of insurance products with the expansion of many health plans into new geographic markets and the development of multiple insurance product lines by indemnity insurers and managed care organizations. As a result, with the exception of sparsely populated areas, most communities now have available HMO, POS, PPO, and indemnity products offering consumers a variety of options in terms of benefits, premiums, copayments, and health care delivery systems.

At the same time, there has been a steady migration from traditional indemnity plans to various managed care products in both the public and private markets. Between 1991 and 1995, the percentage of American workers enrolled in indemnity plans decreased from 59 percent to 35 percent (EBRI, 1997). In 1997, more than 5 million Medicare beneficiaries were enrolled in 336 managed care plans, an increase of more than 100 percent since 1993. Under Medicaid, 13 million, or 35 percent, of all beneficiaries have been enrolled in managed care plans, an increase of more than 170 percent since 1993. The Balanced Budget Act of 1997 will increase those trends by expanding the types of products available to beneficiaries of those two public programs.

Although there is greater choice of health insurance products available in most markets, it is important to note that this choice often is exercised at the level of the group purchaser instead of by individual consumers. Between 1988 and 1997, health plan offerings by moderate- and large-sized employers declined (Gabel, 1997). Those offering three or more plans declined from 35 percent to 32 percent, while those offering only one plan climbed from 41 percent to 44 percent over that period. Notably, the percentage of employees in firms with 200 or more workers who were offered coverage of PPOs and POS plans increased from 12 percent in 1988 to 58 percent in 1997 (KPMG, 1997).

There also is evidence of variation in consumer preferences for various product characteristics. In the Kaiser-AHCPR survey (1996), 70 percent of survey respondents would prefer a high-cost product with a wide range of benefits over a low-cost product with a more limited range of benefits (26 percent). Respondents were more divided over other health product decisions. Fifty-three percent said they would pay more for unrestricted choice of physicians, while 43 percent would opt for a lower cost product that limited choice to a list of physicians. Forty-six percent would pay more to have direct access to any specialist, whereas more than half (51 percent) would choose a lower cost plan that requires a visit to the family physician for a referral (Robinson and Brodie, 1997).

The Commission is troubled by the limited choice of insurance products made available to many consumers through their employer group purchasers. Some of the reduction in choice of plan and product has resulted from conscious decisions by employers to select high-quality products at the best price in the market. In other instances, employers may be seeking to minimize administrative costs associated with multiple offerings. Affording consumers greater choice of plans would allow consumers to select the product that best meets their individual preferences and would encourage health plans to be responsive to consumers' expressed needs. However, the Commission recognizes that, for many consumers, the availability of one plan is better than no

plan at all.

The Commission was unable to achieve consensus on creating a "right" to a consumer choice of health plan or product but it is determined to find ways to encourage and assist employers and other group purchasers in providing consumers with a meaningful choice of health plans and products. Consumer choice of health plans is important and should be provided whenever possible and in a way that is affordable both to employers and consumers. In its final report, the Commission will address policy options to provide greater choice of health plans, products, including encouraging the development of purchasing coalitions and alliances to assist small employers who encounter the greatest difficulty in offering multiple options.

Consumer Choice of Physicians and Other Health Care Providers

The shift from indemnity coverage to managed care arrangements can affect consumers' choice of physicians and other health care providers. In a 1995 study, 41 percent of managed care enrollees who changed health plans over the prior 3 years also changed physicians (Davis et al., 1995). Howver, nearly all covered workers can now choose a health plan that covers non-network providers (AAHP, 1997). In some cases, however, the additional cost of these products or of the option to go out of network effectively puts such choice out of the reach of some consumers.

It also is clear that consumers value some degree of choice of physicians. The 1997 Kaiser/Commonwealth National Health Insurance Survey found that respondents with a choice of physicians registered the highest level of satisfaction with their plans (Davis and Schoen, 1997). A Kaiser-AHCPR survey of consumers identified four reasons why consumers prefer a greater choice of physicians and other health care professionals:

- "So you can see whatever doctor you think is best qualified to treat a particular medical problem" (43 percent);
- "So you can change doctors if you become dissatisfied with the one you're seeing" (24 percent);
- "So you can continue seeing your regular doctor" (20 percent); and,
- "So it's easier to see someone else if your doctor is not available for an appointment" (9 percent).

The most frequently cited reasons speak to consumers' desire to use choice of physicians as a way to obtain quality care. The third is directed toward maintaining relationships with physicians with whom consumers have an existing relationship. In other words, 63 percent of consumers surveyed wanted a choice of physicians so that they can develop and maintain a relationship with a physician they trust to provide them high-quality care.

Therefore, it is important for all health plans and products to maintain an adequate network of

physicians and other health care providers, to provide for continuity of care when consumers change plans, and to allow consumers with special health care needs to have adequate choice of physicians and other health care providers. This can lead to higher consumer satisfaction with providers and their health plans without undermining the efforts of provider groups and health plans to develop organized delivery systems.

The Commission's recommendations seek to build on these trends toward providing greater choice by taking several steps to ensure (1) network adequacy; (2) greater access for women to qualified specialists for women's health services; (3) ease of access to specialists for consumers with complex and serious conditions; and, (4) greater continuity of care for consumers who enroll in new health plans or see their provider dropped from a plan for other than cause.

Provider Network Adequacy

When appropriately structured, a plan using a network of providers can improve the quality and coordination of care delivered to consumers through careful selection and credentialing of providers and through coordination of care by primary care physicians and those with specialty training. The National Association of Insurance Commissioners (NAIC, 1996) has developed standards for provider network adequacy that have been adopted by several States. The Commission believes universal adoption of these standards will improve both the quality of care and consumers' satisfaction with their health plans and their care. Because of its strong desire to maintain the integrity of health plan networks, the Commission has rejected approaches to mandate the inclusion of providers into networks (i.e., "any willing provider" laws) or to require plans to allow enrollees to go out of plan networks at will (i.e., "freedom of choice" laws).

Access to Specialists

Consumers with ongoing health needs often require regular access to physicians and other health care professionals who are specially trained to serve those needs (Bernstein, Dial, and Smith, 1995). This is especially true of those consumers who have disabling or terminal conditions. In such cases, the traditional "gatekeeper" approach used by some health plans can be an impediment to access to quality care and result in unnecessary inconvenience to consumers. The Commission's recommendations are designed to promote consumers' access to appropriately trained specialists while maintaining the integrity of network models of care. Consumers with complex and serious medical conditions who require frequent specialty care should have direct access to a qualified specialist of their choice within a plan's network of providers. Authorizations, when required, should be for an adequate number of direct access visits under an approved treatment plan.

Access to Qualified Specialists for Women's Health Services

Morbidity and mortality associated with breast cancer, cervical cancer, ovarian cancer, and sexually transmitted diseases in women can be significantly reduced through the provision of preventive and routine gynecological services. The U.S. Preventive Services Task Force has

issued recommendations pertaining to the provision of Pap smears, mammograms, and other preventive services for women. Women should be able to choose a qualified provider—including gynecologists and certified nurse midwives—for the provision of an adequate number of visits to cover routine women's health care services.

Transitional Care

Finally, consumers who are undergoing an extensive course of treatment (e.g., chemotherapy or prenatal care) at the time they join a new health plan should be able to continue to see their current physicians for a period of up to 90 days (or through completion of post-partum care). Similarly, such consumers should be able to continue to see a physician who is terminated from a plan's network for reasons other than cause. Sudden interruption of care can compromise the quality of care and patient outcomes. Continuity of care has been shown to increase the likelihood that patients receive appropriate preventive services (O'Malley et al., 1997). Appropriately transitioning of care can protect the quality of that care and improve consumers' satisfaction with a new health plan or product. The Commission's recommendations are designed to ease the impact of these transitions from one health insurance product to another and changes in the composition of health plan networks while maintaining the integrity of network models of care. Consumers who are undergoing a course of treatment for a chronic or disabling condition (or who are in the second or third trimester of a pregnancy) at the time they involuntarily change health plans or at a time when a provider is terminated by a plan for other than cause should be able to continue seeing their current specialty providers for up to 90 days (or through completion of post-partum care) to allow for transition of care.

IMPLICATIONS OF THE RIGHT

Health plans will need to comply with network adequacy standards. Many licensed plans already meet these requirements as laid down by the National Association of Insurance Commissioners (NAIC) in its Managed Care Plan Network Adequacy Model Act. Plans also will need to develop processes to comply with requirements regarding continuity of care and ease of access to specialists within their network of providers.

Consumers will need to exercise their right to choice by using good judgment and providing direct feedback to plans about their level of satisfaction with the network provided for them.

Quality Oversight Organizations will need to incorporate network adequacy standards into their review activities.

REFERENCES

Bernstein AB, Dial TH, Smith MD. Women's reproductive health services in health maintenance organizations. West J. Med 1995;163 [suppl]: 15-18.

Cowan, CA, Braden, BR, McDonnell, PA, et al. Business, households and government: Health spending, 1994. Health Care Finance Rev Summer 1996;17(4)157-178.

Davis K, Collins KS, Schoen C, et al. Choice matters: Enrollees' views of their health plans. Health Affairs Summer 1995:99-112.

Davis K, Schoen C. Testimony before the Advisory Commission on Consumer Protection and Quality in the Health Care Industry; June 25, 1997.

Employee Benefits Research Institute, EBRI Databook on Employee Benefits, Washington DC, 1997.

Gabel JR (KPMG Peat Marwick LLP). Testimony before the Advisory Commission on Consumer Protection and Quality in the Health Care Industry; June 23, 1997.

Kaiser Family Foundation and the Agency for Health Care Policy and Research (AHCPR). Americans as health care consumers: The role of quality information. Princeton Survey Research Associates, October 1996.

KPMG Peat Marwick, Health Insurance Association of America. Sourcebook of Health Insurance Data. Washington, DC; 1996.

National Association of Insurance Commissioners. Managed Care Plan Network Adequacy Model Act. Model Regulation Service; October 1996.

Robinson S, Brodie M. Understanding the quality challenge for health consumers: The Kaiser/AHCPR survey. Journal on Quality Improvement, May 1997;23(5):239-244.

CHAPTER THREE

Access to Emergency Services

STATEMENT OF THE RIGHT

Consumers have the right to access emergency health care services when and where the need arises. Health plans should provide payment when a consumer presents to an emergency department with acute symptoms of sufficient severity—including severe pain—such that a "prudent layperson" could reasonably expect the absence of medical attention to result in placing that consumer's health in serious jeopardy, serious impairment to bodily functions, or serious dysfunction of any bodily organ or part.

To ensure this right:

- Health plans should educate their members about the availability, location, and appropriate use of emergency and other medical services; cost-sharing provisions for emergency services; and the availability of care outside an emergency department.

- Health plans using a defined network of providers should cover emergency department screening and stabilization services both in network or out of network without prior authorization for use consistent with the prudent layperson standard. Non-network providers and facilities should not bill patients for any charges in excess of health plans' routine payment arrangements.

- Emergency department personnel should contact a patient's primary care physician or health plan, as appropriate, as quickly as possible to discuss follow up and post-stabilization care and promote continuity of care.

RATIONALE

In 1995, Americans paid an estimated 96.5 million visits to emergency departments, nearly 37 visits per 100 persons (Stussman, 1997). By tradition, emergency departments (EDs) have handled a spectrum of illness, but have had the primary mission of treating those with acutely serious, even life-threatening, medical conditions. Emergency services can be defined as services that are needed or appear to be needed immediately because of injury or sudden illness that threatens serious impairment of any bodily function, and/or serious dysfunction of any bodily organ or part.

Patients go to the emergency department with nonurgent problems for various reasons. Economic and geographic barriers to other forms of care, the lack of a regular provider, and other factors can and do prompt patients to turn to the emergency department for primary and other nonurgent care. Apart from lack of health insurance coverage, nonfinancial barriers to primary care encourage patients to seek evaluation and treatment in the ED. These include problems with work schedules, access to transportation, and concerns about personal safety (Rask, Williams, Parker, et al., 1994). Physician offices and primary care clinics often have limited hours of operation, while EDs are open 24 hours a day. Medicaid beneficiaries, who have a history of limited access to regular providers, have particularly strong relationships with EDs as the provider of first and last resort. Non-urgent visits to the ED can be costly, contribute to overcrowded waiting rooms, divert resources away from other hospital-based care, and compromise the coordination and continuity of care.

But drawing the line between urgent and nonurgent use of the ED is not an easy decision for physicians, health plans, and consumers. Criteria—both prospective and retrospective—for appropriate ED use are in many ways inadequate. By one criterion, a patient's ED visit might be deemed appropriate, and by another, not so (Lowe and Bindman, 1997). Health care professionals do not agree among themselves about the need for urgent care among emergency department patients (Gill, Reese, and Diamond, 1996). In a survey of 56 hospital EDs, 5.5 percent of patients initially classified by triage nurses as nonurgent were later admitted to the hospital from the ED (Young, Wagner, Kellerman, et al., 1996). Studies estimate that those presenting with nonurgent problems to the ED range from 6.3 percent (Cunningham, Clancy, and Cohen, et al., 1995) to 54.2 percent (Stussman, 1997) of ED visits.

To better manage care and costs in the ED setting, indemnity and managed care plans use a range of tools that includes requirements for prior authorization and imposition of higher cost-sharing for use of out-of-network emergency departments. A 1989 survey of HMO medical directors found coverage policies for ED use across the HMO industry to be fairly uniform (Kerr, 1989). Unless the condition is life-threatening, patients must obtain prior authorization before seeking emergency care services in 80 percent of the responding HMOs, and 38 percent limited their coverage to the EDs of selected network hospitals. A study undertaken by the Center for Health Policy Studies shows that private indemnity insurers have adopted many of these same practices in their fee-for-service arrangements (PPRC, 1996).

A growing set of State and Federal laws and regulations clarify and protect consumers' access to appropriate emergency services. The Emergency Medical Treatment and Labor Act (EMTALA) requires all Medicare participating hospitals to evaluate whether a patient has an emergency medical condition and, if so, to stabilize the patient. The Balanced Budget Act of 1997 requires health plans participating in Medicare or Medicaid to reimburse for emergency services using a "prudent layperson" standard. Numerous States also have adopted this standard for access to emergency services. The Commission's recommendation seeks to create uniformity in all States.

IMPLICATIONS OF THE RIGHT

Health care providers. Physicians and other health care providers will need to work to educate consumers about the appropriate use of emergency department services while working to increase the hours and locations of primary care clinics and other facilities to ease access to such services outside of emergency departments. Emergency department personnel need to make strong efforts to ensure the continuity of care of emergency patients by communicating with patients' primary care providers. Efforts should be made to assist consumers with language, communication, or other barriers.

Health plans. Health plans need to expand consumer education efforts and, when it is within their control, expand hours and location of primary care facilities to facilitate access to such services outside of emergency departments. Plans need to ensure that their coverage and payment policies are consistent with the "prudent layperson" standard.

Consumers. Consumers need to become more familiar with the location and hours of nonemergency care settings and strive to make greater use of such facilities when appropriate. Consumers should communicate with their providers and plans to understand any restrictions on their access to emergency services.

REFERENCES

Cunningham PJ, Clancy CM, Cohen WJ. The use of hospital emergency departments for nonurgent health problems: A national perspective. Med Care Res Rev 1995;52(4):453-474.

Gill JM, Reese CL, Diamond JJ. Disagreement among health care professionals about the urgent care needs of emergency department patients. Ann Emerg Med 1996;28(5):474-479.

Kerr HD. Access to emergency departments: A survey of HMO policies. Ann Emerg Med 1989; 18(3):274-277.

Lowe RA, Bindman AB. Judging who needs emergency department care: A prerequisite for policy-making. Am J Emerg Med 1997;15(2):133-136.

Physician Payment Review Commission. Managing Medicare's fee-for-service program. 1996 Annual Report to Congress. Washington, DC: PPRC;1996:196-199.

Rask KJ, Williams MV, Parker RM, et al. Obstacles predicting lack of a regular provider and delays in seeking care for patients at an urban public hospital. JAMA 1994;271:1931-1933.

Stussman BJ. National hospital ambulatory medical care survey: 1995 emergency department survey. Advance data from vital and health statistics (no. 285). Hyattsville, MD: National Center for Health Statistics; 1997.

Young GP, Wagner MB, Kellermann AL, et al. Ambulatory visits to hospital emergency departments: Patterns and reasons for use. JAMA 1996;276:460-465.

CHAPTER FOUR

Participation in Treatment Decisions

STATEMENT OF THE RIGHT

Consumers have the right and responsibility to fully participate in all decisions related to their medical care. Consumers who are unable to fully participate in treatment decisions have the right to be represented by parents, guardians, family members, or other conservators.

In order to assure consumers' right and ability to participate in treatment decisions, physicians and other health care professionals should:

- Provide patients with sufficient information and opportunity to decide among treatment options consistent with the informed consent process. Specifically,
    - Discuss all treatment options with a patient in a culturally competent manner, including the option of no treatment at all.
    - Ensure that persons with disabilities have effective communications with members of the health system in making such decisions.
    - Discuss all current treatments a consumer may be undergoing, including those alternative treatments that are self-administered.
    - Discuss all risks, benefits, and consequences to treatment or nontreatment.
    - Give patients the opportunity to refuse treatment and to express preferences about future treatment decisions.
- Discuss the use of advance directives—both living wills and durable powers of attorney for health care—with patients and their designated family members.
- Abide by the decisions made by their patients and/or their designated representatives consistent with the informed consent process.

To facilitate greater communication between patients and providers, health care providers, facilities, and plans should:

- Disclose to consumers any factors—including method of compensation, ownership of or interest in health care facilities, or matters of conscience—that they know or should have known could influence advice or treatment decisions.

- Assure that provider contracts do not contain any so-called "gag clauses" or other contractual mechanisms that restrict health care providers' ability to communicate with and advise patients about medically necessary treatment options.

- Be prohibited from penalizing or seeking retribution against health care professionals or other health workers for advocating on behalf of their patients.

RATIONALE

Consumers depend on physicians and other health care professionals to provide them with expert consultation and advice on how to stay healthy or how to cure or palliate their health and medical problems. Unlike many other consumer transactions, the asymmetry of information between consumer and health care provider often is great. Decisionmaking also often occurs at a time of illness, which can undermine the patient's ability to act most effectively in his or her own interest.

Patient and Provider Communication

Relationships between consumers and health care professionals are most rewarding and likely to result in positive outcomes when they are characterized by open communication and active participation of patients in the treatment process. Patient participation in treatment is an essential part of compliance, and compliance improves the effectiveness of care and treatment.

The benefits of patient participation go beyond just the anticipated therapeutic effect of the intervention (Czajkowski and Chesney, 1990). For example, the Coronary Drug Project Research Group (1980), which studied the efficacy and safety of several lipid-lowering drugs, found that even among patients who only took placebos, good adherers had a much lower 5-year mortality rate (15 percent) than did poor adherers (24.6 percent).

Patient participation in treatment decision making also leads to improved satisfaction with care and better quality of life. For example, in a study of patients with early breast cancer, it was found that those who believed they were more responsible for treatment decisions and had more choice of treatment reported higher quality of life than those who perceived themselves as less in control of the treatment decisions (Street and Voigt, 1997).

To participate in decisionmaking about their care, consumers must have complete information about treatment options—including the alternative of no intervention—as well as the risks, benefits, and consequences of such options. Yet evidence suggests that clinical practice often falls short of these expectations. A 1988 study of hospitalized patients found that physicians discussed test or treatment rationale in only 43 percent of cases and alternatives in 12 percent of cases (Wu and Pearlman, 1988). Physicians shared with patients information about benefits in 34 percent of cases and risks in 14 percent of cases.

The continued development of communications technologies to help consumers more fully understand their treatment options and to evaluate the potential risks and benefits of treatments should be encouraged. For example, the use of videos to assist men with prostate cancer evaluate the risks and benefits of surgery versus a "watchful waiting" strategy (Wennberg) and to help men with benign prostatic hypertropy sort out options for treatment (Wagner et al., 1995).

Increasingly, effective communication between health care professionals and patients demands some degree of cultural competence. By the year 2000, nearly one-quarter of the U.S. population will be members of racial or ethnic "minority" groups; this will grow to 47.5 percent by the middle of the next century. Cultural competence refers to the "demonstrated awareness and integration of three population-specific issues: health-related beliefs and cultural values, disease incidence and prevalence, and treatment efficacy" (Lavizzo-Mourey and Mackenzie, 1996). Effective communication for people with communication disabilities may require health care providers to provide auxiliary aids and services and remove certain communication barriers.

It also is imperative that providers be aware of and comply with their patients' decisions with respect to advance directives. Once a patient makes a decision, the health care team should respect this treatment choice. Yet there is clear evidence that this is not happening in far too many instances. Knaus et al. (1995) studied 4,301 patients hospitalized in 6 hospitals and found that physicians often were unaware of their patients' wishes. In 47 percent of cases, physicians reported that they did not know of their patients' expressed desire for a "do not resuscitate" order. In another study focusing on nursing home residents transferred to hospitals, Davis, Southerland, Garrett, et al. (1991) found that medical treatment was consistent with advance directives in 75 percent of the 96 cases studied.

Organizational and Contractual Issues

There are a variety of organizational and contractual factors that also may influence communication between patients and providers. These include financial arrangements and contractual restrictions or sanctions that may inhibit the free exchange of information.

Much attention has focused in recent years on the potential effects of providers' financial incentives on treatment. Methods of compensating physicians can be a powerful mechanism to change provider practice, either to improve the quality of care provided to consumers or to

reduce the costs of that care. But poorly designed compensation arrangements also can result in inappropriate use (including both overuse and underuse) and barriers to care.

All methods of compensating physicians and other health care providers create some form of incentive for behavior. Various approaches are used to offset the potential adverse effects of compensation arrangements. For example, fee-for-service systems may use utilization review mechanisms to temper incentives toward overutilization of health care services. Capitation systems may incorporate measures of quality and consumer satisfaction to minimize incentives toward overutilization. Similarly, salaried arrangements may use bonuses to encourage higher provider productivity and exemplary performance.

In 1996, the Health Care Financing Administration promulgated rules concerning the use of certain types of financial arrangements on behalf of health plans serving Medicare or Medicaid beneficiaries. These rules stipulate that compensation arrangements "may not include any direct or indirect payments to physicians or groups as an inducement to limit or reduce necessary services furnished to an individual enrollee who is covered under the managed care organization's contract." These regulations also require disclosure of information about arrangements that transfer substantial financial risk to the health care provider. If the compensation methods used places the physician or physician group at substantial financial risk, then the health plan must survey enrollees about access and satisfaction with the quality of services, and institute adequate and appropriate stop-loss protections.

In addition to financial incentives, contract rules that restrict providers' ability to advise patients about medically necessary treatment options have been the subject of much concern. Health care providers must be able to advocate for their patients without constraint or fear of reprisal. A report by the General Accounting Office (GAO, 1997) reported: "Of the 529 HMOs in our study, none used contract clauses that specifically restricted physicians from discussing all appropriate medical options with their patients. Two-thirds of responding plans and 60 percent of the contracts submitted had a nondisparagement, nonsolicitation, or confidentiality clause that some physicians might interpret as limiting communication about all treatment options. However, contracts with such business clauses often contained anti-gag language stating that the physician should not misconstrue the contract of a specific provision as restricting medical advice to patients or that the physician should foster open communication." As of mid-1997, 25 States had prohibited the use of such clauses in managed care contracts with physicians and legislation was pending in 23 other States (Health Policy Tracking Service, 1997). In December 1996, HCFA banned the use of gag rules under the Medicare program and in February 1997, HCFA took similar action regarding health plans' participating in Medicaid.

IMPLICATIONS OF THE RIGHT

Consumers must take a more active part in the treatment decision process. Information can be empowering, but navigating the health care system requires patient effort, from completing

advance directives to preparing questions for an office visit. This requires that the consumer ask questions, understand and give informed consent, and become a full partner in treatment decisions with his or her health care provider.

Health care providers also have the central role in ensuring the patient's participation in treatment decisions, including compliance with informed consent. They will need to improve their skills in providing information about the medical and scientific evidenc underlying different treatment options to patients and their families; strive to overcome cultural and language and communication barriers; and keep abreast of the latest and best available treatment options. At the same time, they will need to do a better job of listening to their patients and following their decisions, including the decision to forego treatment or certain types of treatment. Health care providers should assume this responsibility well before a patient reaches a hospital door. To hold the trust of patients, providers will need to disclose financial incentives which may introduce bias into treatment decisionmaking and to avoid such incentives when the balance is tipped against the patient. To be above any potential bias, providers must avoid self-referral arrangements that can cloud their professional judgment. And, finally, health care providers are and should be the most effective advocates for their patients' rights.

Health care facilities and plans must create and maintain an environment supportive of consumer participation in treatment decisions. In the office practice, this means ensuring adequate visit time for patients and providing support for shared decisionmaking programs when questions about care linger, arise after hours, or require further explanation. Health plans can play a significant role in educating patients on how to get the most out of their visit with a health care provider. They can arrange for translator services for patients and continuing education courses for providers to assure cultural and language competency. By statute, health plans and hospitals have obligations to educate the public about the use of advance directives. As importantly, once advance directives are signed, these documents must become part of the patient's medical record and must move with the patient from care setting to care setting. In establishing provider compensation arrangements, health plans and facilities must be vigilant in guarding against the unintended, negative consequences of financial incentives by implementing programs to monitor quality of care and patient satisfaction. The nature of these incentives ought to be disclosed to patients and providers. In contracting with health care providers, plans and facilities should not restrict the provider's ability to discuss treatment options with the patient and not take reprisal upon the health care provider who serves as patient advocate.

REFERENCES

Coronary Drug Project Research Group. Influence of adherence to treatment and response of cholesterol on mortality in the Coronary Drug Project. N Engl J Med 1980;18:1038-1041.

Czajkowski SM, Chesney MA. Adherence and the Placebo Effect. In Schumacher, SK, Schron EB, Ockene JK, et al., editors. The handbook of health behavior change. New York: Springer Publishing Company; 1990.

Davis M, Southerland LI, Garrett JM, et al. A prospective study of advance directives for life-sustaining care. N Engl J Med 1991;324:882-8.

General Accounting Office. Report to congressional requesters. Managed care: Explicit gag clauses not found in HMO contracts, but physician concerns remain. August 1997.

Health Policy Tracking Service. Issue brief: bans on gag clauses. April 1997.

Lavizzo-Mourey R, Mackenzie ER. Cultural competence: Essential measurements of quality for managed care organizations. Ann Intern Med 1996;124(10):919-921.

Street RL, Voigt B. Patient participation in deciding breast cancer treatment and subsequent quality of life. Med Decis Making 1997;17:298-306.

Wu WC, Pearlman RA. Consent in medical decision-making: The role of communication. J Gen Intern med 1988;3:9-14.

CHAPTER FIVE

Respect and Nondiscrimination

STATEMENT OF THE RIGHT

Consumers have the right to considerate, respectful care from all members of the health care system at all times and under all circumstances. An environment of mutual respect is essential to maintain a quality health care system.

Consumers must not be discriminated against in the delivery of health care services consistent with the benefits covered in their policy based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Consumers who are eligible for coverage under the terms and conditions of a health plan or program must not be discriminated against in marketing and enrollment practices based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

RATIONALE

Consumers want to be treated with respect and they want to be treated fairly. An environment of mutual respect is essential to maintain a quality health care system. Incidences of discrimination—real and perceived—mar the relationship between consumers and their health care professionals, plans, and institutions. Multiple consumer surveys (Levinson et al., 1997; Davis et al., 1995; Edgeman-Levitan and Cleary, 1996) have found that many consumers' complaints about the current health care system have their root in the perception that people believe they are not being treated with respect.

Respect has been defined as recognizing a "person's capacities and perspectives, including his or her right to hold certain views, to make certain choices, and to take certain actions based on personal values and beliefs" (Faden and Beauchamp, 1986). Manifestations of disrespect in the health care setting described by consumers in recent research (Levinson et al., 1997) and interviews include: poor communication with their doctor, feeling rushed or ignored, lack of dignity during examinations, experiencing extensive waiting room delays, receiving inadequate explanations or advice, having inadequate time with the doctor during routine visits, feeling that complaints are not taken seriously by providers, and feeling that providers are more concerned withholding down the cost of medical care than with giving the best medical care. Conversely,

consumers defined respectful treatment as that which takes into consideration the values, preferences, and expressed needs of the patient. In addition, consumers wanted providers to communicate well, to be respectful of the patient's time, and to give emotional support to alleviate the patient's fear and anxiety.

In order to extend consumers the respect they deserve, members of the health care industry should strive to:

- Provide consumers with assurances that disrespect or discrimination of any kind is intolerable.
- Provide consumers with information regarding existing laws prohibiting disrespectful or discriminatory treatment.
- Provide consumers with an appropriate amount of time to fully discuss their concerns and questions.
- Provide consumers with reasonable assistance to overcome language (including limited English proficiency) or physical or communication barriers.
- Provide consumers with a timely notice and explanation of changes in fees or billing practices.
- Avoid lengthy delays in seeing a patient; when delays occur, explain why they occurred and, if appropriate, apologize for such delays.

A key element of respectful and fair treatment is protection against discrimination in marketing, enrollment and the delivery of health care services based on race, ethnicity, national origin, religion, sex, age, mental or physical disability, sexual orientation, genetic information, or source of payment.

Sex. Disparities in medical treatment based on sex have been documented in a number of areas, including: diagnosis and treatment of coronary artery disease (Beery et al., 1995), kidney transplantation and dialysis, heart transplantation, cardiac catheterization, and diagnosis of lung cancer (AMA Council on Ethical and Judicial Affairs, 1991). Researchers have found that women are less likely to have diagnostic testing, even when functional disability and risk are higher. Women's complaints are seen as less urgent, and fewer referrals follow as a result of this belief (Tobin et al., 1987). Disparities have also been found in the quality of the doctor-patient relationship. For example, one-quarter of women (compared with 12 percent of men) reported that they have been "talked down to" or "treated like a child by a physician," and 17 percent of women (compared with 7 percent of men) had been told that a medical condition they experienced was "all in their head" (The Commonwealth Fund, 1993; Horton, 1995).

Race, ethnicity, national origin, and religion. Discrimination on the basis of race, ethnicity, national origin, or religion in the provision of health care has also been well documented. There is evidence of disparities in the quality of care, access to health care (because of language or geographic barriers), and the amount of care given to minorities as compared with others (Kahn et al., 1994; Giles et al., 1995; Rosenbaum et al., 1997; Smollar, 1988). In the case of facilities or individuals who accept Federal funds, Federal civil rights statutes prohibit the denial of services; the provision of a different service or services in a different manner from those provided to others; and the segregation of or separate treatment of individuals in any matter related to receiving services (Office of Civil Rights, 1990).

Age. Discrimination against consumers based on their age also occurs in the health care industry including: less aggressive treatment for elderly women with breast cancer and lower than average referral rates for mental health services in older people (Nattinger et al., 1992; Osteen et al., 1992; Ayanian et al., 1993). The Age Discrimination Act of 1972 also prohibits discrimination based on age by any institution or health care provider who accepts Federal funds.

Sexual orientation. Gay and lesbian patients have received reduced care or have been denied care because of their sexual orientation (AAPHR, 1994). Discrimination against gay/lesbian consumers has sometimes been compounded by fears of HIV.

Disability status. There is an extensive history of discrimination against people with disabilities and chronic illnesses that has led to action by Federal and State Government. The landmark Americans with Disabilities Act of 1990 (ADA) prohibits discrimination against individuals with real or perceived disabilities in employment, public services, public accommodations, communications, and employer-provided health insurance. The Health Insurance Portability and Accountability Act of 1996 prohibits the exclusion of an individual from the group insurance market for more than 12 months based on a preexisting medical condition.

Despite passage of these landmark laws, not all Americans living with disabilities or poor health have access to health coverage or may not be able to secure coverage at a cost they believe is fair or affordable. This is particularly true for consumers attempting to purchase coverage in the individual insurance market. Research into further refinements in the insurance market is needed to assist these individuals. The Commission strongly urges insurers, public and private purchasers, State and Federal Governments, and others to explore all policy options to make health coverage available and affordable to Americans who wish to obtain it, especially those who are living with mental or physical disabilities.

Finally, despite recent improvements, many health care facilities remain inaccessible to individuals with disabilities (Savage, 1997). The Commission believes that elimination of physical and communication barriers in health care facilities should be a higher priority for government agencies charged with enforcing the ADA.

Source of payment. The health care system currently is undergoing an historic transformation in which low-income Medicaid beneficiaries are being enrolled into private health plans. While this is a positive development in terms of access for traditionally vulnerable populations to high-quality care, it is almost certain to create additional tensions that could be manifest in discrimination. Providers who agree to accept Medicaid beneficiaries must provide equal access, care, and waiting times to those patients. It will be vitally important for State and Federal agencies to closely monitor the provision of care to Medicaid beneficiaries as they move into new health plans.

IMPLICATIONS FOR THE HEALTH CARE INDUSTRY

Consumers will need to be vigilant in reporting instances of discrimination based on the factors discussed in this chapter. Consumers also must extend the same level of respect to health care providers and others in the health care system that they demand of same. An environment of mutual respect is essential to a healthy relationship between consumers and those who care for them.

Health care professionals and other health workers have the most direct contact with patients and, therefore, have the greatest responsibility to treat health care consumers with respect and to ensure that they do not discriminate. nondiscrimination. Providers have a responsibility to listen to patients and take their concerns and complaints seriously. Providers also have a responsibility to monitor their treatment of patients to assure they are treated with respect and nondiscrimination and to correct problems when they occur.

Health care facilities that renovate existing facilities or construct new ones must meet a high standard of access in order to avoid discriminating against persons with disabilities. While there is no ADA requirement to "retrofit" existing facilities to make them accessible, there is a responsibility to remove "readily achievable" physical and communication barriers. All health care providers should assess the level of access in their medical facilities and take steps to provide effective communication and unimpeded physical access to the maximum extent possible.

Health plans will need to examine the standards and incentives that exist within their systems that may inadvertently discourage providers from attending to the interpersonal aspects of health care quality that can be manifest as disrespect. Consumers enrolled in health plans with defined networks of providers should have access to their plans' participating providers, without regard to the source of their coverage (e.g., Medicare, Medicaid, employer-sponsored plan).

Quality oversight organizations should utilize tools that allow accurate measurement of dimensions of health care quality that reflect consumer concerns about being treated with respect. Public disclosure of these findings, together with measurements of clinical quality of care, cost, benefit, and other salient information can allow consumers to determine the relative importance

they place on such information and make their purchasing decisions accordingly.

Health care worker education and training programs need to recognize and act upon the need for improvements in communication skills by providers. Receiving inadequate explanations and advice, having inadequate time to receive answers to questions, and failure to attend to the need for emotional support can have adverse consequences on health outcomes (Bame et al., 1993; Patterson et al., 1991; Juncos, 1990). Similarly, education and training programs need to develop and implement course content addressing the significance of cultural attitudes on the effectiveness of health care and the importance of being sensitive to the varying needs of people with disabilities, including those with sensory or cognitive disabilities, who often require auxiliary aids or extra time and plain-language explanation to ensure effective communication. Health plans, hospitals, and other large institutional providers are encouraged to have on-site interpreters for any language population that exceeds a specified standard (e.g., 5 percent or more) and telephone interpreter services for other language minorities. Written material provided to patients should also be translated for the larger linguistic groups.

REFERENCES

AMA Council on Ethical and Judicial Affairs. Genetic disparities in clinical decision-making: Council report. 15(4) January 1991; p. 25-35.

American Associations of Physicians for Human Rights. Anti-gay discrimination in medicine: Results of a national survey of lesbian, gay and bisexual physicians. San Francis; 1994.

Beery TA. Diagnosis and treatment of cardiac disease: Gender bias in the diagnosis and treatment of coronary artery disease. Heart & Lung. November 1995;24(4).

The Commonwealth Fund. The commonwealth fund survey of women's health. New York: July 1993.

Davis K, Collins KS, et al. Choice matters: Enrollees' views of their health plans. Health Affairs, Summer 1995;9-112.

Edgeman-Levitan S, Cleary PD. What information do consumers want and need? A synthesis of research to date, plus interviews with health plan managers and consumer advocates. Health Affairs, Winter 1996;15(4):42-56.

Faden R, Beauchamp T. A history and theory of informed consent. New York: Oxford University Press, 1986. p. 8-9.

Giles WH, Anda RF, Casper ML, et al. Race and sex differences in rates of invasive cardiac procedures in US hospitals. Arch Intern Med 1995;155.

Horton JA, ed. The women's health data book: A profile of women's health in the United States. Washington, DC: Elsevier; 1995.

Kahn KL, Pearson ML, et al. Health care for black and poor hospitalized medicare patients. JAMA 1994;27(1).

Levinson W, Roter DL, et al. Physician-patient communication: The relationship with malpractice claims among primary care physicians and surgeons. JAMA February 19, 1997;277(7);553-559.

Office of Civil Rights. Fact Sheet. U.S. Department of Health and Human Services; 1990.

Rosenbaum S, Serrano R, et al. Civil rights in a changing health care system, Health Affairs Jan–Feb 1997.

Savage E. U.S. Department of Justice. Verbal communication; September 1997.

Smollar D. Success of Indochinese students may vary with ethnic factors. Los Angeles Times 1988 Feb 16.

Tobin JN, et al. Ann Internal Med. 1987;107.

CHAPTER SIX

Confidentiality of Health Information[1]

STATEMENT OF THE RIGHT

Consumers have the right to communicate with health care providers in confidence and to have the confidentiality of their individually identifiable health care information protected. Consumers also have the right to review and copy their own medical records and request amendments to their records.

In order to assure this right:

- With very few exceptions, individually identifiable health care information should be disclosed for health purposes only, including the provision of health care, payment for services, peer review, health promotion, disease management, and quality assurance.

- Disclosure of individually identifiable medical information without written consent should be permitted in very limited circumstances where there is a clear legal basis for doing so. Such reasons include: medical research for which an institutional review board has determined anonymous records will not suffice, investigation of health care fraud, and public health reporting. In such instances, notification of the disclosures should be made to the individual upon request.

- To the maximum feasible extent in all situations, non-identifiable health care information should be used unless the individual has consented to the disclosure of individually identifiable information. When disclosure is required, no greater amount of information should be disclosed than is necessary to achieve the specific purpose of the disclosure.

- Health providers, facilities, and plans should develop procedures to ensure that when sensitive services (e.g., mental health, substance abuse, reproductive services, or

[1]In the context of this chapter, health care information is defined as "any information, whether oral or recorded, in any form or medium, that is created or received by a health care provider, health plan, public health authority, employer, life insurer, school, university, health care clearinghouse; and relates to the past, present, or future physical or mental health or condition of an individual, the provision of health care to an individual, or the past, present, or future payment for the provision of health care to an individual."

treatment of sexually transmitted diseases) are involved, standard administrative techniques do not inadvertently disclose information to individuals other than the patient.

RATIONALE

The legal right to confidentiality of health care information and its essential role in the delivery of quality health care has been recognized by the United States Supreme Court, lower Federal and State courts, and Federal and State lawmakers. Similarly, a health care provider's obligation to protect the confidentiality of health information is universally recognized. The assurance that consumers' health information will remain confidential is "fundamental to effective diagnosis, treatment and healing" (Shalala, 1997).

At the same time, the quality of the health care system also depends on the regular exchange of information between providers, employers, plans, public health authorities, researchers, and other users. The changing structure of the health care system and rapid advances in information technology and medical research have increased the demand for and supply of health information among traditional users such as the treating physician, and new users, such as large networks of providers, information management companies, quality and utilization review committees, and independently contracted service providers. Concerns have been raised that under the current system of information exchange, various entities can access individually identifiable information without sufficient security safeguards and consent requirements.

Other activities undertaken to improve quality and efficiency may present new risks to the confidentiality of health information. For example, quality oversight activities by plans, providers, accreditation bodies, and regulatory agencies require detailed information about the treatment and benefit status of individual consumers. The growing role of employers in workforce health issues has also contributed to the confidentiality debate.

Congress has made repeated attempts to enact a comprehensive Federal confidentiality law but has, to date, been unsuccessful. The web of protections at the Federal and State level that has evolved in the absence of a comprehensive law leaves many aspects of health information unevenly protected. Specialized Federal protections already exist through statutes that address substance abuse, Medicaid beneficiaries, public health, research, government records, and those living with disabilities.

Several States have enacted comprehensive laws and an effort is currently underway at the National Association of Insurance Commissioners to draft a Protected Health Information Model Act for States. Other safeguards have evolved outside of the legislative arena. Accreditation bodies have incorporated requirements for confidentiality policies and patient consent (JCAHO 1996; NCQA 1997; URAC 1996) and continue to collaborate on security and confidentiality issues (JCAHO/NCQA Joint Session, 1997).

The Health Insurance Portability and Accountability Act of 1996 (HIPAA) required the Secretary of Health and Human Services to submit to the Congress detailed recommendations on: (1) the rights that an individual who is a subject of individually identifiable information should have; (2) the procedures that should be established for the exercise of such rights; and (3) the uses and disclosures of such information that should be authorized or required (Public Law 104-191). On September 11, Health and Human Services Secretary Donna Shalala presented those proposals to the Congress (Shalala, 1997). Under the terms of HIPAA, if Congress fails to enact Federal confidentiality legislation by August 1999, the Secretary of HHS is required to promulgate regulations setting confidentiality standards.

The Secretary recommends a comprehensive Federal confidentiality law that would apply "floor preemption," meaning that the law would require that all States comply with a minimum set of confidentiality requirements but would not preempt stronger State laws.

Section 262 of HIPAA also requires the Secretary of HHS to adopt standards by February 1998 for electronic transmission of financial and administrative health care transactions (including information about claims, eligibility, payment, and injury), unique health identifiers (for individuals, employers, plans, and providers), and security.

The Commission believes that it is essential to establish a comprehensive confidentiality framework and encourages the Congress to move forward expeditiously.

IMPLICATIONS OF THE RIGHT

Health plans, health providers, employers, and other group purchasers should examine existing confidentiality protections to safeguard against improper use or release of individually identifiable information. The Commission does not intend to impede employers or providers from complying with duties established by law.

Law enforcement officers, medical researchers, and public health agencies should examine their existing policies to ensure that they access individually identifiable information only when absolutely necessary and provide proper safeguards to assure confidentiality.

Consumers should become more aware of the content of their medical records and pay particular attention to requests by providers, plans, employers, or others to gain access to those records.

REFERENCES

Hurwit C. Citizen Action. Testimony before the President's Advisory Commission on Consumer Protection and Quality in the Health Care Industry. May 13, 1997.

Joint Commission on Accreditation of Healthcare Organizations, Comprehensive accreditation manual for health care networks; 1996.

Joint Commission on Accreditation of Healthcare Organizations and National Committee for Quality Assurance. Joint Session on Security and Confidentiality of Patient Medical Information. Washington, DC; 1997.

Lowrance W. Privacy and health research: A report to the U.S. Secretary of Health and Human Services; May 1997.

National Association of Insurance Commissioners. Insurance Information and Privacy Protection Model Act (October 1992); Quality Assessment and Improvement Model Act (July 1996); Utilization Review Model Act (October 1996).

National Committee for Quality Assurance (NCQA). Draft Standards for Accreditation; 1997.

Public Law No. 104-191, The Health Insurance Portability and Accountability Act of 1996.

Pyles JC, on behalf of the National Coalition for Patient Rights. The right to medical privacy: An indispensable element of quality health care. Washington, DC; 1997.

Shalala, Donna E. Secretary of Health and Human Services. Confidentiality of individually-identifiable health information: Recommendations pursuant to section 264 of the Health Insurance Portability and Accountability Act of 1996. Submitted to The Committee on labor and Human Resources and the Committee on Finance of the Senate, and The Committee on Commerce and the Committee on Ways and Means of the House of Representatives. September 11, 1997.

URAC National Network Accreditation Standards (April 1996).

CHAPTER SEVEN

Complaints and Appeals

STATEMENT OF THE RIGHT

All consumers have the right to a fair and efficient process for resolving differences with their health plans, health care providers, and the institutions that serve them, including a rigorous system of internal review and an independent system of external review.

Internal appeals systems should include:

- Timely written notification of a decision to deny, reduce, or terminate services or deny payment for services. Such notification should include an explanation of the reasons for the decisions and the procedures available for appealing them.

- Resolution of all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare (i.e., 72 hours).

- A claim review process conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved. Reviews should be conducted by individuals who were not involved in the initial decision.

- Written notification of the final determination by the plan of an internal appeal that includes information on the reason for the determination and how a consumer can appeal that decision to an external entity.

- Reasonable processes for resolving consumer complaints about such issues as waiting times, operating hours, the demeanor of health care personnel, and the adequacy of facilities.

External appeals systems should:

- Be available only after consumers have exhausted all internal processes (except in cases of urgently needed care).

- Apply to any decision by a health plan to deny, reduce, or terminate coverage or deny payment for services based on a determination that the treatment is either experimental or investigational in nature; apply when such a decision is based on a determination that such services are not medically necessary and the amount exceeds a significant threshold or the patient's life or health is jeopardized[1].

- Be conducted by medical and health care professionals who are appropriately credentialed with respect to the treatment involved and subject to conflict of interest prohibitions. Reviews should be conducted by individuals who were not involved in the initial decision.

- Follow a standard of review that promotes evidence-based decisionmaking and relies on objective medical evidence.

- Resolve all appeals in a timely manner with expedited consideration for decisions involving emergency or urgent care consistent with timeframes consistent with those required by Medicare (i.e., 72 hours).

RATIONALE

Health care consumers, like other purchasers, have concerns about the service they receive. Unlike other consumers, however, health care consumers have special interests at stake—the length and quality of their lives. How consumer complaints are addressed has a significant impact on the quality of health services provided and on the satisfaction of consumers with the individuals and institutions that provide them.

Fair and efficient procedures for resolving consumer complaints about their health care serve many purposes. First and foremost, enhanced internal and external review processes will assist consumers in obtaining access to appropriate services in a timely fashion, thus maximizing the likelihood of positive health outcomes. Second, they can be used to bridge communication gaps between consumers and their health plans and providers, and to provide useful information to all parties regarding effective treatment and consumer needs. Third, the opportunity for consumers to be heard by people whose decisions significantly touch their lives evidences respect for the dignity of consumers as individuals and engenders their respect for the integrity of the institutions that serve them.

Properly structured complaint resolution processes should promote the resolution of consumer concerns as well as support and enhance the overall goal of improving the quality of health care. Internal and external complaint and appeal processes should be:

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[1]The right to external appeals does not apply to denials, reductions, or terminations of coverage or denials of payment for services that are specifically excluded from the consumer's coverage as established by contract.

- Timely.
- Fair to all parties.
- Administratively simple.
- Objective and credible.
- Accessible and understandable to consumers.
- Cost and resource efficient.
- Subject to quality review.

Internal and external complaint and appeal processes should not interfere with communication between consumers and their health care providers. For example, in instances where consumers and their providers agree that a service should be reduced or terminated, no written notification of such decisions is needed. Additionally, health care providers who participate in the complaint and appeal processes on behalf of patients should be free from discrimination or retaliation. Likewise, consumers who file a complaint against a provider or plan should be free from discrimination or retaliation.

For the purposes of this chapter, the following definitions are used for the terms "complaints" and "appeals":

Complaint. A "complaint" is any expression of dissatisfaction to a health plan, provider, or facility by a consumer made orally or in writing. This includes concerns about the operations of providers, insurers, or health plans, such as waiting times, the demeanor of health care personnel, the adequacy of facilities or the respect paid to consumers, and claims regarding the right of the consumer to receive services or receive payment for services previously rendered, including the organization's refusal to provide services the consumer believes he or she is entitled to.

Appeal. An "appeal" is a consumer's request for a health plan, facility, or provider or other body to change an initial decision. An appeal process is a procedure for reconsideration of a specific determination made by a health provider, facility or plan.

Current Resolution Processes

Currently, many different procedures are used by group purchasers, health plans, and provider organizations to respond to consumer complaints. Licensed health plans are subject to numerous State and Federal laws, and many also comply with the standards of private accrediting bodies (e.g., NCQA 1997; JCAHO 1996; AAHCC/URAC 1996). Virtually all private and public health plans provide consumers with some form of complaint resolution process. The Commission does not intend by these recommendations to weaken existing consumer protections. These include:

State Licensed Insurance Products. States traditionally have regulated the benefit structure, solvency, rates, and claims process of indemnity insurance companies doing business in the State. Some State insurance regulations require health insurers doing business in the State to

provide certain complaint procedures to enrollees (Abraham, 1990). In addition, all 50 States have laws licensing or governing HMOs doing business in the State separate from their laws regulating indemnity insurance products. Many States' laws are based on the model HMO law drafted by the National Association of Insurance Commissioners (NAIC, 1996), which requires HMOs to establish complaint procedures approved by the State's insurance commissioner. An estimated 30 States have some specified complaint procedures that HMOs must follow and at least 7 States now require an expedited appeal for denials of urgently needed care.

ERISA Plans. All employers offering health benefits to their employees through managed care organizations or traditional indemnity insurers must comply with requirements of the Employee Retirement Income Security Act. ERISA requires private employer-provided health benefit plans to disclose certain information to plan participants, to report information to the Federal government, and to pay benefits that are promised under the plan. ERISA regulations generally require employer health plans to approve or deny claims within 90 days and to approve or deny appeals of claims denials within 60 days. Although ERISA health plans are required to establish and disclose complaint and appeals procedures to participants, and to notify participants of claims denials, the plans are not required to provide a particular complaint procedure (Butler and Polzer, 1996). An internal reconsideration of denied claims is stipulated but appeals may be decided by the same plan administrators that initially denied the claim. Determinations must be in writing and state specific reasons for the decision.

Medicare. Under the Medicare fee-for-service system, fiscal intermediaries and carriers must provide a two-step internal review and notification of their final decision before a beneficiary is entitled to seek reconsideration from the Social Security Administration's payment division and the Health Care Financing Administration (Kinney, 1996). Medicare provides a graded appeal process that includes a hearing before an administrative law judge and administrative appeals council review for claims under Part A (hospital coverage) if the amount in controversy is more than $100; and under Part B (physical and outpatient coverage) if the claims are more than $500. Claims under Part A and Part B for more than $1,000 are entitled to judicial review.

HMOs that participate in Medicare are required to provide meaningful internal procedures for resolving complaints about the quality of care, untimely provision of care, or the improper demeanor of health care personnel (Stayn, 1994). HMO decisions to deny coverage for certain treatment, referral outside a plan, or reimbursement for emergency or out-of-area care are subject to an external review and administrative appeal. HCFA has contracted with a private organization, the Center for Health Dispute Resolution, to perform these reconsiderations (Richardson, Phillips, and Conley, 1993). After external review, a Medicare beneficiary enrolled in an HMO who is "dissatisfied by reason of his failure to receive any health service to which he believes he is entitled and at no greater charge than he believes he is required to pay" has a right to Social Security administrative review for controversies more than $100 and judicial review for controversies more than $1,000.

Medicaid. The Federal Medicaid statute requires State agencies to provide beneficiaries with a fair hearing and an administrative appeal when their eligibility or requests for services are denied or not acted upon within reasonable time. These State agency determinations can be challenged in State court under State administrative procedure acts or in Federal court. In addition, HMOs that contract to serve Medicaid beneficiaries must establish an internal complaint procedure that will resolve disputes promptly. These internal procedures are subject to review and approval by the State. Medicaid HMO enrollees have the same rights to administrative appeal as do fee-for-service enrollees but are required to exhaust internal complaint procedures before seeking a hearing before the State agency.

Federal Employees Health Benefit Program. Federal employees and their dependents receive coverage through private insurance carriers, including more than 300 HMOs. Under the FEHBP complaint resolution process, enrollees may bring disputes concerning benefits or services to the Office of Personnel Management for review after asking the plan to reconsider its initial denial and failing to receive a satisfactory reply. OPM seeks to determine whether the enrollee or family member is entitled to the services or supply under the terms of the contract.

Other Approaches. The federal HMO Act requires that to be a "federally qualified HMO," a plan must provide meaningful procedures for hearing and resolving complaints between subscribers and the plan. The written procedures must be easily understood and provided upon request. HMOs are not required to comply with the Act's requirements but may do so to obtain favored status. Other approaches to complaint resolution exist in the Department of Defense's health programs, including the Civilian Health and Medical Program of the Uniformed Services (CHAMPUS).

IMPLICATIONS OF THE RIGHT

Assuring that all consumers have access to both internal and external processes that satisfy the requirements of this right will require action on virtually every level of the health care industry.

Enhancing Internal Review Systems. Health plans will need to examine their existing internal review systems to assure that consumers receive a timely, understandable notice of decisions to deny, reduce, or terminate treatment or pay claims; notice of the reasons for that determination and of the complaint and appeals procedures available to them; and expedited processes for certain types of cases. While there do not appear to be reliable data indicating how many health plans currently provide internal complaint procedures, most apparently do. Thus, implementation of a general right to file internal complaints, to appeal within a health plan, and to receive a response will not require a majority of health plans to change their current practices significantly. It will be important for quality oversight organizations (State licensure programs, Federal certification programs, and private accrediting bodies) to assure that their standards and review processes adequately address internal complaint and appeal processes of health plans.

Establishing Independent External Appeals Systems. Additional analysis must be done to identify the most effective and efficient methods of establishing the independent external appeals function. Issues to be considered include: mechanisms for financing the external review system; sponsorship of the external review function; design of review processes to assure evidence-based decisionmaking; qualifications of reviewers; consumer cost-sharing responsibilities (e.g., filing fees); and methods of overseeing and holding external appeals entities accountable. It will also be important to establish an ongoing evaluation mechanism to assess the impact of the external appeals process on access to appropriate services, rates of consumer disputes, litigation rates, consumer satisfaction, and costs. The evaluation mechanism should also assess the impact of certain design characteristics on the effectiveness and efficiency of the external appeals process.

REFERENCES

Abraham KS. Insurance Law and Regulation 92-139;1989.

American Accreditation Health Care Commission/Utilization Review Accreditation Commission (AAHCC/URAC). National network Accreditation Standards. Washington, DC; April 1996.

American Association of Health Plans. Health plans announce policies on appeals rights and emergency care coverage. Washington, DC; January 1997.

American Bar Association, Commission on Legal Problems of the Elderly, Roundtable on the resolution of consumer disputes in managed care. Washington, DC; 1997.

American Hospital Association: State Issues Forum. Designing consumer protection standards. Chicago; 1996.

American Psychiatric Association. Principles for the provision of mental health and substance abuse treatment service: A bill of rights. Washington, DC; 1997.

Atkins G, Bass L and K. ERISA preemption: The key to market innovation in health care. New York: Corporate Health Care Coalition; 1995.

Butler P, Polzer K. Private sector health coverage: Variation in consumer protections under ERISA and state law. Washington, DC: National Health Policy Forum, George Washington University; June 1996.

Citizen Action. Campaign for health security managed care principles. Washington, DC; January 1997.

Committee on Choice and Managed Care. Assuring public accountability and information, improving the Medicare market: Adding choice and protections. Washington, DC: Institute of Medicine; 1996.

Dame L, Wolfe SM. Serious problems for older Americans in health maintenance organizations. Public Citizen's Health Research Group; May 1995.

Families USA. HMO consumers at risk: States to the rescue. Washington, DC; 1996. Update March 1997.

Joint Commission on Accreditation of Health Care Organizations, 1996. Accreditation manual for hospitals. Chicago; 1996.

Kinney ED. Resolving grievances in a managed care environment. Health Matrix 1996 winter; 6:147-165.

Kinney ED. Protecting consumers and providers under health reform: An overview of the major administrative law issues. Health Matrix 1995;5:83-138.

Medicare Rights Center. Medicare appeals and grievances: Strategies for system simplification and informal consumer decisionmaking. New York; 1996.

National Association of Insurance Commissioners (NAIC). Health Carriers Grievance Procedure Model Act. October 1996.

National Committee on Quality Assurance (NCQA). Standards for members' rights and responsibilities. Surveyor Guidelines; April 1, 1997.

Physician Payment Review Commission. Annual report to Congress 1997. Washington, DC; 1997.

Public Policy and Information Fund of New York. The managed care consumers' bill of rights. New York; October 1995.

Richardson DA, Phillips J, Conley D Jr. A study of coverage denial disputes between Medicare beneficiaries and HMOs. Pittsford (NY): Center for Health Dispute Resolution, Network Design Group, Inc.; September 1993.

Rodwin MA. Managed care and consumer protection: What are the issues? Seton Hall Law Review Winter 1996;26:1007-1054.

Stayn SJ. Securing access to care in health maintenance organizations: Toward a uniform model of grievance and appeals procedures. Columbia Law Review June 1994;94:1674-1720.

CHAPTER EIGHT

Consumer Responsibilities

STATEMENT OF RESPONSIBILITIES

Greater individual involvement by consumers in their health care provides consumers with more control over the outcome of that care. The Commission encourages consumers to strive to meet as many of the following responsibilities as possible:

- Take responsibility for maximizing healthy habits, such as exercising, not smoking, and eating a healthy diet.
- Become involved in specific health care decisions.
- Work with health care providers in developing and carrying out agreed-upon treatment plans.
- Disclose relevant information and clearly communicate wants and needs.
- Use the health plan's internal complaint and appeal processes to address concerns that may arise.
- Recognize the reality of risks and limits of the science of medical care and the human fallibility of the health care professional.
- Be aware of a health care provider's obligation to be reasonably efficient and equitable in providing care to other patients and the community.
- Become knowledgeable about his or her health plan coverage and health plan options (when available) including all covered benefits, limitations, and exclusions, rules regarding use of network providers, coverage and referral rules, appropriate processes to secure additional information, and the process to appeal coverage decisions.
- Make a good-faith effort to meet financial obligations.
- Abide by administrative and operational procedures of health plans, health care providers, and Government health benefit programs.
- Report wrongdoing and fraud to appropriate resources or legal authorities.

RATIONALE

In providing consumers with a set of rights and protections, the Commission believes that individual consumers must assume certain responsibilities. Responsibilities create benefits not only for individual consumers and their families, but also for the health care system and society as a whole. Improved health status reduces medical costs for the patient, the payer and for society.

Increased patient responsibility can improve consumers' sense of self-worth. For example, increased responsibility among individuals living with disabilities has resulted in increased independence for that population (Rodwin, 1994; National Health Council, 1995). In fact, this is the principle behind the independent living movement, where people with disabilities live in their homes with personal assistant services rather than in institutions. Individuals report that increased responsibility for their health has led to improved self-esteem and a greater sense of empowerment.

Promoting consumer responsibility is an essential component of the effort toward involving consumers directly in decisionmaking about their health and medical care. Consumers often perceive that the medical professionals who care for them are acting in a condescending or paternalistic manner. They resent being put in a position of dependence and being treated as if they are infantile and object to the presumption that they are incapable of making choices themselves (Rodwin, 1994).

While the Commission believes that consumers must assume certain responsibilities, it also recognizes that reasonable accommodations must be made for numerous consumers with disabilities. For example, some individuals with physical and mental disabilities require assistance with self care; for some individuals with mental disabilities, noncompliance with treatment regimes is a manifestation of their disability; and some individuals with mental and physical disabilities are unable—due to their disability—to clearly communicate their wants and needs and, therefore, rely on the assistance of a designated representative. In each case, the health care system must recognize these issues and accommodate these needs. The Commission also recognizes that there are many other factors, such as occupational hazards, language, and income status, that many pose significant barriers to consumers meeting these responsibilities.

Consumers who are able should take the opportunity to educate themselves with respect to the specifics of their benefit coverage and to learn how to access the health care and services available to them as a result of that coverage. This includes:

- Reading and understanding written information that explains benefit coverage
- Reading and understanding information that describes health plan processes and procedures to follow when seeking care by a physician, hospital, or other provider.
- Seeking information or clarification of information from the health plan as necessary.

- Using the health plan's processes for addressing complaints or grievances when disputes with providers or health plan procedures arise.

Consumer responsibility is particularly relevant to the broad right to information established in this Consumer Bill of Rights and Responsibilities (see Chapter One). The Right to Information requires the disclosure of information to consumers either directly or upon request on such things as benefits, cost-sharing, complaints and appeals processes, licensure, accreditation, and performance measures. The Right to Information will improve health outcomes only to the extent that consumers have a choice of health plans and use that information in exercising the choice.

Although there is significant value in promoting the consumers' participation in their own health care by increasing their level of responsibility, it is important to set limits on the amount of responsibility expected. The patient's responsibility to comply with medical advice is limited by the principle of informed consent (Benjamin, 1985). The patient retains the right to choose whether to follow medical advice or not, as long as he or she is willing to accept the health outcome consequences that may result from noncompliance, and the noncompliance does not adversely affect the public (Brock and Wartman, 1994).

Consumers do not have a duty to be subjected to a treatment regime they have good reason to avoid—for instance, one whose negative side effects outweigh its benefits (Mayer, 1992), or when excessive medication in an institutional setting is used to "control" residents. Most consumer responsibilities do not extend to those who are incompetent to make decisions including infants, those who are judged to be mentally incompetent, and comatose patients (Emson, 1995; Mayer, 1992; National Health Council, 1995).

In addition, certain high-risk behaviors (smoking, illegal drug use) are addictive and cannot be considered fully under the volitional control of the individual consumer. Caution must be used to avoid "blaming the victim." For example, Bayer (1996) notes that during the history of the AIDS epidemic, "the emphasis on personal responsibility was often associated with condemnation of those whose sexual or drug-using behavior had exposed them to HIV, as well as with calls for invasion of privacy and deprivations of liberty."

Compliance with agreed-upon treatment protocols is a particularly important consumer responsibility. Noncompliance with the taking of medication has particular implications for the health status of consumers. Noncompliance includes taking too much medication, taking medication not prescribed, not taking medication prescribed, altering the prescribed dosage, or altering the time between doses.

Finally, it is important to recognize that while consumers should seek to assume the responsibilities discussed in this report, many factors influence consumers' acceptance of medical advice. Some are related to the health care system itself and others are related to the patient's individual psychology. Imanaka, Araki, et al. (1993) identified patient dissatisfaction with their health care providers and plans as a primary cause of patient noncompliance. Several

studies have identified inadequate provider-consumer communication as a contributing factor (Imanaka, 1993; Ross, 1991; Donovan and Blake, 1992; Sluijis, Kok, et al., 1993). This leads to situations where:

- The patient and the prescriber have a different understanding of what the patient is supposed to do.
- The patient lacks information or understanding about the disease, pathology, or symptoms.
- The patient does not understand the correct purpose of the intervention.
- The patient and the health care provider have insufficient time to discuss the full range of issues concerning compliance.

Noncompliant patients also may have underlying psychiatric disorders. Yellowless and Ruffin (1989) found that 40 percent of patients who experience a life-threatening asthma episode have psychiatric disorders. Patients often are trying to balance the requirements of their prescribed medical regimen with other aspects of their life (Donovan and Blake, 1992). Finally, some patients choose not to comply with medical instructions as a way of expressing their attempts to cope with their disease; as a reaction to the way they have been treated by doctors; or as a way of fighting the system by breaking its "symbolic" rules (Ross, 1991).

IMPLICATIONS OF THE RESPONSIBILITIES

Consumers will have to play an active role in the treatment and management of their health. Consumers will need to ask more questions of their health care providers, insurers, and institutions. They will need to express their wishes and desires clearly to those who care for them and to their family members in the event of incapacity; this should be done before an incapacity occurs. They will need to make sure that they understand a treatment regimen that is prescribed for them before they agree to follow it. Once they have made such an agreement, consumers will need to make every effort to comply and, if they cannot, to notify their provider of their desire or need to change that regimen. Consumers will need to recognize the financial and societal impact of their health care decisions and their health care choices should reflect this consideration.

Health care providers will need to communicate more clearly with their patients and their patients' families about diagnoses, treatment options, and treatment protocols. They will need to make greater efforts to ensure that those matters are clearly understood and agreed to. They will need to work with their patients to ensure that treatment regimens are possible to follow and that changes in treatment are made when possible to meet patients' needs or demands.

Health plans will need to consider ways to encourage greater communication between consumers and health care professionals, including incentives for such communication and acceptance of treatment regimens.

REFERENCES

Adams ML. The public health impact and economic cost of smoking in Connecticut—1989. Conn Med April 1994;58(4):195-8.

American Hospital Association. Designing consumer protection standards: State issues forum. Washington, DC; October 1996.

American Medical Association. Code of medical ethics 1996–1997. Chicago, Illinois; 1997.

Arras JD. Noncompliance in AIDS research. Hastings Center Report September/October 1990; 24-32.

Bame S, Petersen N, et al. Variation in hemodialysis patient compliance according to demographic characteristics. Soc Sci Med October 1993;37(8):1035-43.

Bayer R. AIDS prevention: Sexual ethics and responsibility. New Eng J of Med June 6, 1996; 334(23).

Beers MK, Sliwkowski, et al. Compliance with medication orders among the elderly after hospital discharge. Hosp Formul July 1992; (27).

Benjamin J. Lay obligations in professional relations. J Med Philos 1985;10(1):85-103.

Brock, DW, Wartman SA. When competent patients make irrational choices. In: Beauchamp T, Walters L, editors. Contemporary issues in bioethics. 4th ed. Belmont, CA:Wadsworth Publishing; 1994.

Brody H. Patients' responsibilities. In: Reich W, editor. Encyclopedia of bioethics. Revised ed. New York, NY: Simon and Schuster Macmillian; 1995.

Cebrun AJ. Consumer responsibility in the HMO environment. J Health Care Poor Underserved 1994;(5)3.

Col N, Fanale JE, Kronhom P. The role of medication noncompliance and adverse drug reactions in hospitalizations of the elderly. Arch Intern Med 1990;(150):841-845.

Donovan JL, Black DR. Patient non-compliance: Deviance or reasoned decision-making? Soc Sci Med 1992;(34)5:507-513.

Edy DE. The individual vs society: Resolving the conflict. JAMA May 8, 1991;(265)18: 2399-2406.

Emson HE. Rights, duties, and limits of autonomy. Cambridge Q Healthc Ethics 1995;(4):7-11.

Harris J, Holm S. Is there a moral obligation not to infect others? BMJ November 1995;(311) 4:1215-1217.

Imanaka Y, Araki S, et al. Effects of patient health beliefs and satisfaction on compliance with medication regimens in ambulatory care at general hospitals. Nippon Eiseigaku Zasshi June 1993; (48)2:601-11.

JCAHO. 1996 Comprehensive accreditation manual for health care networks.

Jensen GJ, Lorish CD. Promoting patient cooperation with exercise programs: Linking research, theory, and practice. Arth Care and Res Dec 1994;(7)4.

Juncos LI. Patient Compliance and angiotensin converting enzyme inhibitors in hypertension. J Cardiovascular Pharmacol 1990;(15) Suppl 3: S22-5.

Macdonald M, Meyer KC, Essig B. Health law Guidebook Series. New York: Matthew Bender, 1996.

Mayer M. Patients' Duties. J of Med and Phil 1992;(17):541–555.

National Highway Traffic Safety Administration. Web page, 1997.

National Health Council. Principles of patient rights & responsibilities. Washington, DC; January 1995.

NCQA. Standards for member's rights and responsibilities. 1997 Surveyor Guidelines.

Public Citizen Health Research Group Health Letter. Vol 11, no 6; June 1995.

Rodwin M. Patient accountability and quality of care: Lessons from medical consumerism and the patients' rights, women's health and disability rights movements. Am J Law Med 1994;(20)147.

Ross FM. Patient compliance: Whose responsibility? Soc Sci Med 1991;(32)1:89-94.

Sharkness CM, Snow DA. The patient's view of hypertension and compliance. Am J Prev Med 1992;8(3).

Shiffman S. Refining Models of dependence: Variations across persons and situations. Br J Addict May 1991;(86)5:611-15.

Sluijs EM, Kok GJ, et al. Correlates of exercise compliance in physical therapy. Phys Ther Nov. 1993;(73)11.

Sullivan SD, Kreling DH, Hazlet TK. Noncompliance with medication regimens and subsequent hospitalizations; A literature analysis and cost of hospitalization estimation. J Res Pharmac Econom 1990;(2):19-33.

TenHave, Loughlin. Responsibilities and rationalities: Should the patient be blamed? Health Care Anal 1994;(12):112-117.

Tuohey JF. Moving from autonomy to responsibility in HIV-related healthcare. Camb Q Healthc Ethics 1995;(4):64-70.

Weiss KB, Wagner DK. Changing patterns of asthma mortality: Identifying target populations at high risk. JAMA 1990;(264):1683-7.

Yellowless PM, Ruffian RE. Psychological defenses and coping styles in patients following a life-threatening attack of asthma. Chest 1989;(95):1298-1303.