PATIENT’S BILL OF RIGHTS

On June 29, 2001 the United States Senate passed S. 1052, the Bipartisan Patient’s Protection Act. This legislation, requiring fundamental reform to the managed care industry, was co-sponsored by Senators Kennedy (D-MA), John Edwards (D-MA), and John McCain (R-AZ). The legislation passed by a vote of 59-36, and now the activity on the legislation will move to the House of Representatives.

As written and passed by the Senate, S. 1052 applies to all individuals with private health insurance, including non-federal government plans, such as state and local governments, that purchase health insurance. However, a State can opt out of the federal requirements if they demonstrate to the Secretary of Health and Human Services that they “substantially comply” with the federal requirements. The bill has several “access to care” provisions that would enhance the care of persons diagnosed with cancer. Specifically:

A) Access to Specialists. The bill requires that timely access to specialists be provided by health plans. If a health plan does not have the requisite specialists, the plan must provide access to a nonparticipating specialist at no additional cost to the beneficiary.

B) Continuity of Care. Persons with “ongoing medical conditions” are permitted to have their care coordinated by a specialist. These conditions include those which require medical care over a prolonged period of time such as life-threatening, degenerative, potentially disabling, or congenital conditions. The specialist providing this care would be able to treat, refer, and authorize medical services.

C) Access to Clinical Trials. The bill requires that health insurers cover federally approved or funded clinical trials for individuals with serious or life-threatening diseases. Included in this requirement is coverage of patient care costs associated with clinical trials funded by the National Institutes of Health, the Department of Defense, the Department of Veterans Affairs, as well as Federal Drug Administration-approved clinical trials. Further, during the debate on the Senate floor Senator McCain introduced an amendment related to clinical trials. The amendment, referred to as a “Sense of the Senate” Resolution, expressed the intent of Senator McCain that individuals with life-threatening diseases have the ability to participate in federally funded or approved clinical trials. The Sense of the Senate Resolution passed by a vote of 89-1. While the resolution itself has no specific legislative power, it does place a strong Senate vote on the record. This will be of critical importance if the legislation that emerges from the House floor does not address access to clinical trials to the same extent that the Senate bill does. Essentially, the vote of the Senate on this issue will provide leverage to the Senate Conferees on the bill to ensure that the will of the Senate prevails.

Many view the House of Representatives bill, H.R. 2315, as substantially weaker than the Senate-passed bill. In the context of cancer, the House bill that is presently in play provides similar access to specialist provisions. However, there is some difference in the clinical trial provision in that the legislation would only extend to cancer clinical trials and not other life-threatening diseases. It is the hope of Speaker Hastert (R-IL) that the legislation will be considered in the House prior to the August recess that is scheduled to begin on August 3, 2001.

The President has weighed in on the Patient’s Bill of Rights debate. White House spokesmen have indicated that the Senate-passed bill improved considerably over the introduced version; however, they have not indicated support for the Senate-passed bill. Further, the President has indicated that the legislation provides greater protections for lawyers than it does for patients. The White House has issued principles for a Patient’s Bill of Rights that provide some indication of how he will consider the components of any final measure sent to him for passage or veto. The principles are:

• Patient protections should apply to all Americans.
• Patient protections should be comprehensive.
• Patients should have a rapid medical review process for denials of care.
• The patient review process should ensure that doctors are allowed to make medical decisions and patients receive care in a timely manner.
• Federal remedies should be expanded to hold health plans accountable.
• Patient protection legislation should encourage, not discourage, employers to offer health care.

HEALTH CARE FINANCING ADMINISTRATION TO UNDERGO SOME CHANGES

Secretary Tommy Thompson has announced reforms for the Health Care Financing Administration that include

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renaming and restructuring the agency. The new name, Centers for Medicare and Medicaid Services (CMS), is immediately effective. In addition, the agency is being reorganized into three Centers. The Center for Beneficiary Choices will focus on beneficiary education and information, the management of Medicare-managed care plans, and grievance/appeals initiatives. In addition, the Center for Medicare Management will address issues relative to the fee-for-service program. The Center for Medicaid and State Operations will work with programs administered by the states. In addition, CMS will invest $36 million over 3 years to establish standardized bookkeeping software for a single agency-wide system.

**White House Sets Bar for Medicare Reform**

On July 12, 2001 President Bush announced the criteria that will guide his Administration in efforts regarding Medicare reform. The President’s principles are as follows:

- All beneficiaries should have the option of a subsidized prescription drug benefit as part of modernized Medicare.
- Medicare should provide better health insurance options, like those available to all Federal employees.
- Modernized Medicare should provide better benefits for preventive care and serious illnesses.
- Today’s beneficiaries and those approaching retirement should have the option of keeping the traditional plan with no changes.
- Medicare legislation should strengthen the program’s long-term financial security.
- The management of the traditional Medicare plan should be strengthened, so that it can provide better care for seniors.
- Medicare’s regulations and administrative procedures should be updated and streamlined, while continuing to reduce fraud and abuse.
- Medicare should encourage high-quality health care for all beneficiaries.

In discussing his principles the President indicated that the lack of a drug benefit is one of the most glaring omissions in the current program and indicated that over 98% of employer-sponsored health plans pay for prescription drugs. In addition, he cited the importance of access to preventative care and outlined examples of where Medicare had lagged behind the private sector, sometimes by decades, in providing important preventative services. As an example, the information issued by the White House cited the fact that while prostate cancer screening tests were widely available in private health plans by the late 1980s, Medicare coverage did not kick in until 2000.

As a first step to achieving Medicare reform, the President also announced a new national drug discount program to begin in 2001, a drug discount card. The drug discount plan combines the purchasing clout of millions of seniors to negotiate lower prices than under the current system. The government will set standards for private entities, such as Pharmacy Benefit Managers (PBMs), to offer the discount card. These companies will be required to demonstrate to the government that they will negotiate discounts with numerous pharmacies and that drugs from every major class would be included in their card program. The President believes that this option will provide immediate help to millions of seniors. The Administration believes that it can act on this issue immediately in the absence of legislation. Democrats have criticized this initiative saying that it falls short of what is necessary to address the immediate issue of a drug benefit for older Americans. In addition, several chain pharmacies have initiated litigation against the Administration, as they believe that no regulatory authority exists to proceed with this type of program in the absence of a legislative mandate.

**FY 2002 Appropriation**

The Administration has proposed a budget of $23.1 billion for the National Institutes of Health (NIH) for FY 2002. This represents a 13.4%, or $2.75 billion, increase over 2001. The House and Senate Budget Resolutions assumed this funding level in the resolutions passed in May. However, this level of funding falls short of what has been urged by advocates to sustain the doubling of the NIH over five years—$3.4 billion. It is anticipated that the markup of the House and Senate Labor-Health and Human Services (HHS) Appropriations bills will occur in September after Congress returns from the August recess.

One overarching appropriation issue for the NIH relates to the salary cap on investigators. Since 1990 language has been included in the Labor-HHS Appropriations bill that would prohibit an institution from using NIH funds to pay the salary of an investigator at a level above the cap. Last year, the cap was raised to $161,200; however, in the FY 2002 budget proposal the Administration has proposed reducing the cap to $145,000. Over 80 organizations have sent a letter to the House and Senate Labor-HHS Appropriations Committees urging that they reject the Administration’s proposal and leave the current salary cap in place.

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