



Overview of 2011 Policy Agenda January 2011

Federal Legislative

Congressional member and party majority changes resulting from the recent elections indicate that there will be significant focus on existing health reform laws. NPAF's efforts going forward will be to stay its course of abiding by its mission to improve access to healthcare for American health consumers. This nonpartisan mission will serve as an NPAF compass during the upcoming year when partisan politics will become increasingly polarized. Thus, NPAF will simply seek to maintain those sections of existing law which benefit health consumers and will seek to amend those sections which do not.

NPAF's activities will be tiered to reflect its priorities relative to the NPAF mission. Activities that are most closely aligned with directly benefitting the healthcare consumer will be placed on Tier 1. Tier 1 activities are those which NPAF will assume a leadership role and dedicate a great amount of its resources. Tier 2 activities are those which are substantially aligned with the NPAF mission. NPAF efforts relative to Tier 2 will involve collaborating with health coalitions whose mission and values closely reflect those of NPAF. Examples of Tier 2 efforts include including: lobbying, NPAF communications, and grassroots mobilization. Finally, Tier 3 activities are those that are tangentially aligned with the NPAF mission. NPAF will merely monitor these activities and resource expenditure will be minimal. Tier 3 priorities involve mostly coalition activity and group sign-on letters.

NPAF will engage in a number of ongoing activities that transcend its daily efforts. A major focus of the National Patient Advocate Foundation (NPAF) Federal Legislative Affairs staff in 2011 will be educating new Members of Congress about the work of both National Patient Advocate Foundation and Patient Advocate Foundation (PAF) through in-person meetings, Capitol Hill briefings and district/state toolkits which will include specific information about the patients served by PAF.

Tier 1

- Maintain Specific Patient Protection and Affordable Care Act (ACA) Provisions
 - Consumer Protections: prohibition on preexisting conditions and programs, such as PCIPs to address access to insurance challenges for

- those with pre-existing conditions; elimination of annual and lifetime limits on coverage; and capping out-of-pocket healthcare expenses
 - Expanded Insurance Coverage: Health Insurance Exchanges and Medicaid expansion
 - Medicare Physician Reimbursement Impact on Patient Access

Tier 2

- Medical Imaging

Tier 3

- Fiscal Year 2012 Appropriations
- Medical Debt Legislation (Bankruptcy protection and COBRA extension)

Federal Regulatory

In 2011, the NPAF Federal Regulatory Affairs department will be focused on growing and maturing Regulatory Education and Action for Patients (REAP), an umbrella coalition of patient advocacy groups established by NPAF in July 2010. The coalition’s goals are to strengthen current relationships and build new relationships with government agencies that are responsible for implementing provisions of the Patient Protection and Affordable Care Act (ACA) and to ensure that implementation of these provisions is patient-centric. REAP’s mission is to communicate the patient perspective on issues to Federal and State regulatory bodies, Congress, health care insurers and others that regulate/develop/manage and/or impact health delivery, coverage, cost and availability to the United States population. The unique expertise of over 40 patient advocacy organizations will help to augment our evaluation efforts. While REAP is focused on the implementation of ACA, it will be engaged in additional regulatory issues outside ACA.

In addition, implementation of the Patient Protection and Affordable Care Act (ACA) will be a top priority for the department as federal health agencies are expected to continue to release proposed and interim final rules related to provisions in the law. The Office of Consumer Information and Insurance Oversight (OCIO) was established by the Department of Health and Human Services (HHS) in 2010 to help implement many provisions included in ACA. In addition, the Centers for Medicare and Medicaid Services have many responsibilities in helping to implement ACA. As a result, NPAF has prioritized building new relationships and strengthening existing relationships with representatives in HHS, OCIO, and CMS. NPAF’s 2011 federal regulatory priorities are outlined below and have been ranked and divided into tiers according to the level of importance. As previously mentioned, the tiers established by NPAF can best be described as follows: tier 1 priorities are NPAF led initiatives that are resource intensive; tier 2 priorities include some coalition work but require distinct NPAF efforts including: lobbying, NPAF communications, and grassroots mobilization. Tier 3 priorities involve mostly coalition activity and group sign-on letters.

Tier

- Regulatory Education and Action for Patients (REAP)
- Patient Protection and Affordable Care Act (ACA) Rules and Regulations
 - Payment Reforms
 - Accountable Care Organizations
 - Bundling
 - Least Costly Alternative
 - Medicare Part D Coverage Gap
 - Healthcare Workforce

Tier 2

- Patient Protection and Affordable Care Act (ACA) Rules and Regulations
 - Prevention and Wellness
 - Comparative Effectiveness Research
- Additional Regulations (Physician Fee Schedule, Hospital Outpatient Prospective Payment System etc)
- Health Information Technology

Tier 3

- Follow-on Biologics
- Value-Based Purchasing

State Government Affairs

The primary focus of the National Patient Advocate Foundation (NPAF) State Government Affairs team in 2011 will be to expand the grass-roots volunteer organization of State Policy Liaisons (SPLs) and Patient Voice Network Volunteers (PVNs) in eight strategic states to position NPAF to have a significant impact in the Presidential election in 2012. The eight states are: Arkansas, California, Florida, Illinois, Michigan, Ohio, Pennsylvania and Virginia. This will be initiated through the implementation of the first annual State Policy Liaisons Advisory Board meeting on February 1, 2011 at PAF headquarters in Hampton, VA. This advisory board will address issues such as what we have successfully accomplished with the program and how we can improve to further engage the volunteers. Our volunteers will extend invitations to other non-profits for NPAF to collaborate with them at the state level in preparation for the 2012 Presidential election. The NPAF State Government Affairs Team will work to expand our volunteer network to a younger group of volunteers through outreach via social media outlets and college based programs. In addition, NPAF will continue to recruit healthcare professionals to the volunteer network; since September 2010, approximately 51.6% of all new volunteers to the NPAF network were healthcare professionals.

The State Government Affairs team will also be working to educate state legislative and state level advocacy contacts on issues relevant to the patients we represent through the publication of white papers utilizing the vast network of scientific and policy advisors that NPAF has at its disposal.

The following policies represent the 2011 priorities for the NPAF State Government Affairs department and have been divided into tiers according to their priority. Tier 1 priorities are NPAF State Government Affairs led initiatives that are resource intensive and involve the engagement of the entire volunteer network. Tier 2 priorities include targeted state level work and include NPAF efforts including lobbying and NPAF communications. Tier 3 priorities involve collaborative work with other advocacy groups and targeted correspondence.

Tier 1

- Expanding volunteer membership in eight targeted states (Arkansas, California, Florida, Illinois, Michigan, Ohio, Pennsylvania and Virginia)
- Tracking of state Medicaid budgets with appropriate intervention when changes are noted
- Assisting in the implementation of high risk pools at state level

Tier 2

- Oral Chemotherapy Parity Legislation

Tier 3

- Expand use of compendium to a minimum of 2-3 per state via state legislative reform activities

NPAF 2011 Federal Legislative Priorities

Tier 1

- **Maintain Specific Patient Protection and Affordable Care Act (ACA) Provisions**

The ACA, signed into law in March 2010, will eventually expand insurance coverage to millions of Americans who are currently uninsured or underinsured. It will also eliminate the use of pre-existing conditions to deny or impose waiting periods on insurance coverage. In addition, the law includes other critically important provisions long supported by National Patient Advocate Foundation, such as the elimination of annual and lifetime limits on coverage and the imposition of a cap on out-of-pocket health care spending. It is clear that efforts will be made in Congress during 2011, and perhaps beyond, to eliminate or curtail some of these favorable developments for patients. NPAF will be closely monitoring legislation in Congress for its impact on patients, poised to strongly oppose proposals which would negatively impact the access of patients to affordable care.

Consumer Protections: Prohibition on Preexisting Conditions and Programs, such as PCIPS, to Address Access to Insurance Challenges for Those with Pre-Existing Conditions

NPAF is also focusing on the temporary high-risk pools, (also referred to as PCIPs) established as part of the health care reform law which will be critically important to patients with pre-existing conditions prior to the elimination of exclusions and waiting periods based on pre-existing conditions in 2014. Although there were early concerns that the \$5 billion allocated for the risk pools may not have provided sufficient funding through January 1, 2014, and there was no provision for additional funding if it was needed, preliminary data indicated that enrollment was much lower than anticipated. However, a January 31 article on PCIPs featured in the newspaper POLITICO states that “high risk pools, so far plagued with lackluster enrollment, are showing signs that they are starting to turn around.” The article quotes Secretary of Health and Human Services Kathleen Sebelius as stating, “Within the past 75 days, enrollment in the federally-run high risk pools has just about doubled. Approximately 10,000 Americans are currently being covered between the state and federally run insurance plans.” An official count of enrollment by state is expected in late February. As difficult as the high risk pools are, any roll-back of the current legislation is likely to make insuring such individuals more challenging, so this group must remain a priority.

While encouraged by this latest development, NPAF is concerned that the six-month period that applicants must be uninsured before being accepted in the new high-risk pools might serve as an impediment to enrollment. NPAF is assessing the need for legislation to address these concerns with the temporary high-risk pools created by the health care reform law. Other specific areas of NPAF consideration regarding PCIPs include gauging CMS’s interest in using the results of the Government Accountability Office’s (GAO) report entitled, “Health Insurance: Enrollment,

Benefits, Funding and Other Characteristics of State High-Risk Health Insurance Pools” in determining how best to increase enrollment, considering the ability of using the \$5 billion earmark to defray premium costs to consumers by utilization of a sliding-scale payment system and initiating regular conversations with CMS’s Office of Consumer Information and Insurance Oversight relative to these issues and reporting back to the Board on same. In summary, NPAF will explore initiatives that might help boost enrollment and will lead efforts to advocate for changes that will encourage enrollment increases. PCIP enrollment increase is an important priority as it is directly correlated to access to care challenges for those with pre-existing conditions and is characterized by strong bipartisan support.

Elimination of Annual and Lifetime Limits on Coverage;

Before the ACA was passed, about 20,000 insured Americans reached the lifetime limits of their coverage each year.¹ A survey conducted by the Kaiser Family Foundation revealed a finding that more employer-sponsored health plans are offering coverage with at least a \$2 million lifetime limit. NPAF understands the importance of lifetime limits for those suffering from chronic, life-threatening and disabling diseases. NPAF will educate legislators on not only the personal financial hardship that these limits create, but on the economic hardships that result from denying care to those who might be productive members of society if treatment were continued. PAF data regarding patients served who have in fact reached the limits will help legislators understand the problem with greater specificity, such as the identification of diseases most likely to be the diagnosis for patients reaching the cap. Because NPAF recognizes limits on coverage may likely be viewed as a prudent business practice by leaders in the health insurance industry, it will work with those leaders to better understand the effect of caps on consumers and on the economy. NPAF will also become better educated on limits of coverage in administering a successful health insurance product. Other strategies such as protected re-insurers not unlike Fannie Mae or Freddie Mac in the housing market may be one solution, although any further government funding will be challenging.

Capping Out-of-Pocket Healthcare Expenses

While the distinction between the insured and the uninsured is often made to identify those who have access to healthcare and those who do not, insurance plans that require high out-of-pocket healthcare expenses frustrates the ability of some insured to access to health care. Their access is limited to the amount they can afford to pay for such care. The ACA has a number of provisions that will begin in 2014 that will address this issue. To assure a greater percentage of insured Americans, premium tax credits and cost-sharing subsidies will make health insurance affordable. They will be available to those with incomes up to 400% of the poverty level (\$43,320 for an individual or \$88,200 for a family of four in 2009). Out-of-Pocket premium expenses will be determined on a sliding income scale. The ACA also provides limits on out-of-pocket for services covered by health plans. According to the Kaiser Family Foundation website, those who purchase health insurance through the exchanges and who have incomes at or below 400% of the poverty level will the out-of-pocket limits will be reduced to one-third of the overall limits for those with incomes 100-200% FPL; by one-half for those with incomes 200-300% FPL; and by two-thirds for those with income 300-400% FPL. Those employed by small employers will find their deductibles

¹ Reed Abelson, “Awaiting Health Law’s Prognosis,” New York Times February , 2011, B1
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for new plans limited to \$2,000 for individuals and \$4,000 for families unless the plan was grandfathered. NPAF recognizes the importance of affordability of health insurance to those with chronic, debilitating and life-threatening diseases and will work to assure the continuance of these protections for the people it serves.

Expanded Insurance Coverage: Health Insurance Exchanges and Medicaid Expansion

NPAF is currently serving with the National Association of Insurance Commissioners (NAIC) on several committees that are charged with drafting language that federal agencies will consider in their quest to educate consumers about health insurance exchange products. Additionally, NPAF is working with members of representatives from the Association of Health Plans as well as key committee members to ensure regulatory or educational language submitted by NAIC or other associations is refined to reflect the suggestions offered by PAF caseworkers in improving consumer documents.

NPAF also has a multitude of activities to stay abreast of efforts that challenge Medicaid expansion sections of the ACA. NPAF is working with State Policy Liaisons (SPLs) to monitor proposed federal legislation that may decrease state Medicaid dollars. It is also monitoring proposed federal language that may redirect Medicaid funds. Finally, NPAF has ongoing communication with SPLs so that they may inform NPAF of state efforts to procedurally encumber Medicaid eligibility or to introduce state legislation to further reduce eligibility.

Monitoring of state policies to detect roll-backs in coverage will be a crucial role for NPAF as individual state coverage variation is likely to increase.

- **Medicare Physician Reimbursement Impact on Patient Access**

National Patient Advocate Foundation is concerned that reductions in Medicare physician payment may adversely affect patients. Legislation was signed into law in early-December 2010 which averted a scheduled 24.9 percent cut to physician reimbursement under a formula known as the Sustainable Growth Rate (SGR). The one-year fix provides a zero percent update in reimbursement levels for 2011. Congress has repeatedly postponed the SGR cuts, but has failed to enact a permanent solution. NPAF supports the one-year fix passed by Congress in December 2010 in order to give Congress time to develop a permanent solution to this problem. A permanent fix to the sustainable growth rate is likely to cost between \$210 billion to \$230 billion over 10 years according to federal actuaries. NPAF encourages Congress to reconsider a series of cascading cuts in Medicare physician reimbursement, in addition to the SGR, that threaten to discourage physicians from accepting Medicare patients.

Last year, 18% of patients contacting Patient Advocate Foundation were insured through Medicare. Because PAF serves such a large number of Medicare beneficiaries, cuts to physician reimbursement are especially troubling since decreased reimbursement to physicians provide them with less incentive to treat Medicare beneficiaries and will ultimately lead to decreased access to necessary care for patients. Patient Advocate Foundation has documentation of medical practices in forty-four states that have closed or stopped seeing Medicare patients in response to continuing Medicare reimbursement difficulties and is beginning a multi-year project to audit PAF data on the impact of

Medicare physician reimbursement on patient access. The decision by some physicians not to accept any Medicare beneficiaries at all because of low payment rates is particularly worrisome for patients living in rural settings and some urban areas that may already have limited access to healthcare providers. Further, the NPAF Medicare patient population tends to live on a fixed income – nearly 67 percent of NPAF Medicare patients have incomes of less than \$23,000. They face challenges with meeting both the coverage gap associated with Medicare Part D, as well as the 20% out-of-pocket expenses incurred with the delivery of any healthcare service reimbursed under basic Medicare coverage.

Over the past several years, Congressional action has temporarily blocked scheduled physician reimbursement cuts from going into effect. Temporary fixes are not an effective or efficient way to address physician reimbursement; a permanent solution needs to be adopted to fix the flawed SGR system. A 2007 American Medical Association ("AMA") survey suggested that 60% of physicians would have been forced to limit the number of Medicare patients they treated had the January 2008 10.1% payment cut gone into effect. Also, between now and 2015, eight in ten physicians said they expect to reduce or delay purchases of new and innovative medical equipment and/or more sophisticated information technology if cuts to Medicare reimbursement occur in the future.

Sustainable Growth Rate. Sections 1848(d) and (f) of the Social Security Act (the Act) require the Secretary to set the physician fee schedule update under the Sustainable Growth Rate (SGR) system. Based on this update system, CMS anticipates further negative updates in later years, absent further Congressional intervention and a revision of the SGR.

NPAF continues to be concerned that the SGR is problematic as it results in negative updates that can negatively impact patient access. The SGR formula fails to consider other factors affecting the actual cost of providing physician services such as growth in the beneficiary population, program changes and utilization factors unrelated to economic trends. NPAF suggests that Congress work with all national healthcare stakeholders to restructure this reimbursement calculation system in order to meet the needs of patients, which do not diminish in slower economies, and to ensure that physician payments increase annually to reflect real increases in the cost of providing patient care. The overriding goal of such efforts should be a permanent SGR fix and NPAF activities will include working collaboratively with provider groups who will take the lead on this issue to assure the issue is described as a patient access issue. To the extent the debate is addressed from this perspective, NPAF proffers a broader network of support for resolution will be forthcoming from the non-profit patient advocate community. NPAF's role as a leader in the advocacy community will seek to build consensus within that community to bring understanding of the nexus between SGR challenges and patient access to healthcare issues.

Nationally, the research through NPAF's Global Access Project (GAP) is tracking and reporting access issues. In 2005, NPAF commissioned a Geographic Access to Care study as part of its Global Access project. This study was published by researchers at the University of North Carolina and summarized the distribution of cancer patients and cancer care providers across regions and population types, paying special attention to potential differences in access to care that might be related to rural location, race, ethnicity or low-income status. The study found that:

Forty-five percent of all rural counties in the study states have no oncology service providers at all – neither a hospital nor a hematology or medical

oncologist...Nearly one-fourth of the urban counties also have no cancer care providers...Eighteen percent of rural counties have hospitals that report providing oncology services, yet there are no oncology physicians located within the county according to the CMS files.

The formula used to determine physician reimbursement under Medicare needs to be replaced with a mechanism to assure that physicians are adequately compensated for providing care to Medicare patients. Otherwise, increasing numbers of Medicare beneficiaries will be unable to access care as more physicians decline to accept Medicare patients. This problem will be most acute, as noted above, in rural areas and some urban counties.

NPAF is currently in consultation with our policy advisors on collaborative activities to address tort reform, also referred to as medical malpractice reform, and health workforce as significant inter-related pieces of the long-term SGR solution. Tort reform efforts that are being considered for future NPAF efforts include studying the benefits of the recently introduced HEALTH ACT -- the Help Efficient, Accessible, Low-cost, Timely Healthcare Act of 2011, The HEALTH ACT caps compensation for pain, suffering, and emotional distress at \$250,000. If the award is intended to be punitive, the cap would then be either \$250,000 or twice the economic damages, whichever is greater. There are currently other legislative proposals being considered in the House and Senate that NPAF is tracking. A mechanism to protect those truly harmed by malpractice from health care and other care costs must be considered as part of the reform package, not unlike those who are at financial risk from co-pays.

NPAF will assure a coordinated, targeted strategic approach in its efforts to address politically-sensitive health workforce issues particularly as they relate to encouraging an expanded role and adequate reimbursement for non-physician practitioners with prescriptive ability, including, but not limited to, nurses, nurse practitioners and physician assistants. One particular area to consider is the provision of billing codes for these practitioners.

Tier 2

- **Medical Imaging**

National Patient Advocate Foundation believes that medical imaging services, such as ultrasound, x-ray, CT scans, and MRIs, are essential tools to help detect stage and treat life-threatening and debilitating diseases like cancer, stroke and heart disease.

The majority of cancer patients served through Patient Advocate Foundation require multiple forms of imaging. NPAF believes that medical imaging saves lives and is concerned that provisions related to medical imaging services contained in the health care reform law may disproportionately impact access to care for patients living in rural and underserved urban communities. The recently passed health care reform legislation sets the utilization rate for medical imaging equipment at 75 percent. That means that reimbursement for the many services involving expensive imaging equipment will be based on the assumption that the equipment is in use 75 percent of the time. In 2009, the

utilization rate was 50 percent. The new rate takes effect next year. Combined with the SGR cuts discussed above and other oncology-specific cuts required in the 2011 Physician Fee Schedule, some physicians may be facing a cascading series of reimbursement cuts that will negatively impact patient access to physicians. NPAF will be closely watching the impact on patients of these cuts to medical imaging services and assessing the need for a legislative adjustment or correction.

NPAF is acutely aware of recent reports of over-utilization of imaging services by providers and supports efforts to remedy this finding. A June 2008 study by the Government Accountability Office (GAO) found that the Medicare Part B program spent \$14.11 billion on imaging services in 2006, up 48% compared to \$6.89 billion in spending in 2000. The report found a connection between in-office imaging and spending growth, with the proportion of Medicare spending on in-office imaging rising from 58% in 2000 to 64% in 2006. Finally, the report found that in 2006 Medicare spending on imaging varied widely by state, from \$62 per beneficiary in Vermont to \$472 per beneficiary in Florida.

NPAF supports the following principles with respect to medical imaging:

Medical imaging saves lives. Medical imaging enables better, less-invasive care which often means easier recoveries and greater patient comfort. Medical imaging often detects critical illnesses at their most curable stage when they are also least costly to treat.

Medical imaging is cost-effective when appropriately prescribed and supported by guidelines. Because of less-invasive care, fewer complications, earlier detection, shorter hospital stays, and better patient management, medical imaging can be an overall cost-saver for patients and for the healthcare system in general. NPAF supports the use of imaging guidelines, specifically those developed by physician specialty societies, which encourage compliance with established guidelines in an effort to reduce unnecessary radiation exposure to patients and unnecessary costs to the nation's health care system. In addition physicians should discuss specialty society guidelines with patients at the time of prescribing. NPAF supports federal funding of grants to medical specialty groups to develop medical imaging guidelines and appropriateness criteria.

Medical imaging is the future. Medical imaging technology provides physicians with a remarkable vision of the body's structure and functioning without surgery and is one of the essential tools of modern medicine. Medical imaging is a core component of the digital revolution enabling productivity gains through electronic health records, rapid access to images, and greater information and flexibility resulting in better outcomes for patients.

Tier 3

Fiscal Year 2012 Appropriations (October 1, 2011 –September 30-2012)

National Patient Advocate Foundation supports federal programs that will advance biomedical research in cancer and other chronic medical conditions. We support programs that are designed to reduce or eliminate health disparities among minority and uninsured patient populations. NPAF also supports programs to assist with cancer screening, prevention, education, detection and treatment, as well as programs designed to study cancer epidemiology.

National Patient Advocate Foundation supports the appropriation recommendations developed by One Voice Against Cancer (OVAC), a collaboration of national non-profit organizations representing cancer patients. As an OVAC member, NPAF urges Congress to appropriate the levels of funding recommended by OVAC for the National Institutes of Health, National Cancer Institute, Centers for Disease Control & Prevention, Food and Drug Administration, and Health Resources and Services Administration programs.

In addition, NPAF historically has worked to assure an appropriations earmark for the Virginia Cares Uninsured Program (VCUP) at Patient Advocate Foundation. The majority leadership of the new House of Representatives has announced that it will not take appropriations bills to the House floor that contain earmarks, and the Senate Republican leadership has announced its opposition to any earmarks. The President stated in his State of the Union address that any legislation arriving on his desk with an earmark will be vetoed thus making it unlikely that the FY 2012 appropriations legislation will contain any earmarks.

- **Medical Debt Legislation (Bankruptcy protection and COBRA extension)**

As noted above, ACA will eventually provide millions of uninsured Americans with access to health insurance coverage, including those with pre-existing conditions, and will eliminate annual and lifetime limits on coverage and cap out-of-pocket spending. These reforms will help in the future to safeguard Americans from medical debt crisis and medical bankruptcy. Some patients, however, are already in, or at risk of, medical debt crisis or may be faced with bankruptcy before the law becomes fully operational in 2014.

As noted in the *2009 Patient Data Analysis Report* of our companion organization, Patient Advocate Foundation (PAF), the number of patients contacting PAF for assistance with managing medical debt remains the largest mission category. Medical debt affects all patient populations, regardless of age, insurance status, and ethnicity. In 2009, almost 65 percent of PAF patients reported debt crisis due to direct medical expenses as their primary health care access issue; of those, approximately 81 percent of these patients were fully insured. For patients, the problem is not just increasing premiums, co-pays, and deductibles, but also caps on benefits and the use of inadequately regulated health care credit cards that result in quick accumulation of medical debt.

While it is the hope that health reform, once fully implemented, will significantly reduce medical debt crisis and medical bankruptcy issues for patients, the need for further reform is necessary. NPAF has in the past supported legislation introduced in the House of Representatives by Representative Carol Shea-Porter (D-NH) and in the Senate by Senator Sheldon Whitehouse (D-RI) that would amend current bankruptcy law adopted in 2005 to allow individuals to once again file medical bankruptcy. That legislation was not acted upon and so died with the last Congress. Rep. Shea-Porter was defeated in her re-election bid.

NPAF will begin conversations with legislators in the House and Senate, including Senator Whitehouse, seeking to have medical debt legislation re-introduced in the new Congress on a bipartisan basis and will work to recruit a robust set of bipartisan cosponsors.

Medical debt legislation can assist patients and their family caregivers who have already accumulated significant debt due to a medical illness. It can provide protection to these individuals over the next several years until the health care reforms are fully implemented in 2014. NPAF supports legislation that would allow individuals to file medical bankruptcy without undergoing a means test, making a bankruptcy filing less expensive and more accessible and that would exempt some portion of property that the debtor uses as a residence, allowing many individuals in medical crisis to stay in their homes.

NPAF also supported legislation (H.R. 5324/S. 3393) in the last Congress introduced in the House by Representative Susan Davis (D-CA) and in the Senate by Senator Sherrod Brown (D-OH) to provide for COBRA continuation coverage until insurance coverage is available to individuals under either an employment-based health plan or through a state insurance exchange under the ACA. NPAF hopes to see this legislation re-introduced in the new Congress on a bipartisan basis so that patients can avoid medical debt by maintaining insurance coverage.

NPAF 2011 Regulatory Priorities

In calendar year 2010, National Patient Advocate Foundation in partnership with Patient Advocate Foundation Regulatory Committee case managers and Larri Short, regulatory counsel at Arent Fox, have drafted and submitted comments on the following proposed rules and regulations: erythropoiesis-stimulating agents (ESAs) in anemia related to kidney disease; electronic health record incentive program; MEDPAC; prescription drug user fee act reauthorization (PDUFA); medical loss ratios; Food and Drug Administration disclosure policies; grandfathered health plans; hospital outpatient prospective payment system; physician fee schedule; risk evaluation and mitigation strategy (REMS); internal claims & appeals and external review process; Pre-existing Condition Insurance Plan (PCIP); planning and establishment of state-level exchanges; health plan efforts to address health literacy needs; accountable care organizations and the Medicare Shared Savings Program; parallel review of medical products; Medicare and Medicaid requirements for long-term care facilities and hospice services; and Medicare Advantage and the Medicare Prescription Drug Benefit Programs for contract year 2012.

In addition, NPAF, as a founding member of the Regulatory Education and Action for Patients (REAP), has coordinated the research and development of comments submitted to federal health agencies. REAP has submitted comments on the Agency for Healthcare Research and Quality (AHRQ)'s Request for Measures of Health Plan Efforts to Address Health Plan Members' Health Literacy Needs, which included nine co-signatories, as well as the Food and Drug Association (FDA) and the Centers for Medicare and Medicaid Services (CMS) Request for Comments on Parallel Review of Medical Products which included twenty co-signatories in addition to three guest signatories. The synergy that REAP affords its members will be expanded upon during the upcoming year as there will be a greater number of regulations that will have significant impact on patients promulgated. REAP will consider a greater number of regulations upon which to comment. REAP is striving to comment on 1-2 regulations per quarter.

The following represent the regulatory priorities identified by NPAF staff, PAF Regulatory Committee members and professional regulatory counsel in Washington, D.C.

Tier 1

- **Patient Protection and Affordable Care Act (ACA) Rules and Regulations**

Implementation of ACA is a top priority for the Federal Regulatory Affairs department at NPAF in 2011. As of December 2010, government agencies have released approximately thirty proposed or interim final rules related to the implementation of ACA and this trend is expected to continue or even accelerate in the years to come. Based on conversations with members of CMS, MedPAC and House of Representative members, NPAF is evaluating the need for legislative remedy to reduce the number of rules that may be published as an interim final rule. NPAF will continue to be very engaged in patient access issues as they relate to ACA; several key issues NPAF will focus on in 2011 include:

Accountable Care Organizations. The *“Patient Protection and Affordable Care Act”* (ACA) promotes the formation and operation of accountable care organizations (ACOs) in an effort to improve the quality of health care services and to lower health care costs. ACOs are comprised of a group of health care providers who provide coordinated care, while receiving payment based on achieved quality goals and outcomes. The essential premise is that more organized, coordinated patient care, combined with increased provider incentives has the ability to improve the overall quality of care while at the same time lowering health care costs. Because ACOs are not part of the rulemaking process but are rather promoted in the form of demonstration projects, NPAF’s role will likely be limited to providing comprehensive comments addressing each area of ACO development, from a strong position of patient choice and therefore prospective enrollment as well as monitoring their effect on the patient population.

As per the ACA, ACOs are to be fully operational by January 2012 and NPAF anticipates that the Centers for Medicare and Medicaid Services (CMS) will release a proposed rule on ACOs in January 2011. Prior to the official release of the proposed rule, NPAF submitted comments to CMS in response to their Request for Information Regarding Accountable Care Organizations and the Medicare Shared Saving Program which was issued November 17, 2010. While NPAF believes in the potential of ACOs to better coordinate and integrate care for Medicare patients, especially those diagnosed with multiple chronic conditions, we are concerned about ACO structure and its impact on patients. Specifically, NPAF calls on CMS to permit patient choice with regard to selecting a particular ACO, to allow patients to benefit from ACO savings through reduced out-of-pocket expenses and for CMS to examine the geographical impact ACOs will have on the rural patient population. NPAF understands that many patients are wary of managed care efforts that restrict their ability to select the provider of their choice. When patients are allowed to choose their provider network, their assurance and faith in the system results in increased protocol adherence and engagement.

NPAF also encourages CMS to examine the geographical challenges that ACOs will present to patients and providers in rural areas. Limited enrollment options, combined with extensive travel distances may inhibit patients from seeking the coordinated, quality care that ACOs strive to

provide. The formation of ACOs should not impact patient access to quality, coordinated managed care. NPAF will continue to examine administrative issues with regard to ACO structure, specifically looking for guidance on how administrative fees will be handled by the primary hospital within a particular ACO, as well as ACO payment standards.

Bundling. Our current healthcare system is based on paying healthcare providers for the services they provide – it is commonly referred to as fee-for-service payment. Some argue that fee-for-service has contributed to our escalating healthcare costs as well as poor care coordination. Bundled payment, also known as episode-based payment, refers to a payment system in which a single payment for all services related to a treatment or condition, possibly spanning multiple providers in multiple settings, is made by an insurer. One bundle that is often referenced is the single payment made for coronary artery bypass graft (CABG) surgery. The bundle includes presurgical services, facility and physician fees for the inpatient surgical procedure, and follow-up care.

While the RAND Corporation has estimated that bundling for selected widely used conditions and procedures could help reduce health care spending by 5.4% by 2019, NPAF is concerned that many serious illnesses including cancer may not fall neatly into “episodes.” Attempting to develop a bundled payment for cancer care which is highly variable would almost certainly have a negative impact on patient access to care.

Least Costly Alternative. The least costly alternative (LCA) policy allowed the Centers for Medicare and Medicaid Services (CMS) to limit payments for Medicare Part B drugs to the “least costly alternative” in a therapeutic class. In April 2010, CMS rescinded the “least costly alternative” policy; however, the Medicare Payment Advisory Commission (MedPAC) has provided recommendations to Congress which would give the Secretary of Health and Human Services the authority to apply least costly alternative policies in setting payments for items and services covered under Medicare Parts A and B. NPAF is concerned that re-instituting LCA will negatively impact patient access to necessary treatment options. Because MedPAC has decided not to include this item in its next report, NPAF’s role will likely involve monitoring the issue during the first half of 2011.

Medicare Part D Coverage Gap. The “*Patient Protection and Affordable Care Act*” (ACA) provides immediate relief to Medicare Part D beneficiaries who reach the coverage gap, or “donut hole” and closes the coverage gap completely by 2020. Beneficiaries reach the coverage gap once they have reached a limit on covered Part D prescriptions under their Medicare plan and subsequently assume all out-of-pockets costs until reaching the catastrophic threshold. In 2010, all Part D enrollees who reach the coverage gap will receive a one-time, tax-free \$250 rebate check, which is designed to provide relief to these out-of-pocket costs. Beginning in 2011, the coverage gap will shrink annually until it is closed in 2020.

In addition, beginning in January 2011, when non-low income subsidies beneficiaries fall into the coverage gap they will receive a 50% discount when buying Medicare Part D covered brand-name drugs. The dollar value of the manufacturer discount counts towards the beneficiary’s out-of-pocket costs.

NPAF has long supported the elimination of the Part D coverage gap as it places undue burden on patients, many of whom live on fixed incomes. Approximately eighteen percent of all patients served by Patient Advocate Foundation (PAF) in 2009 were insured through Medicare and nearly 67

percent of them have incomes of less than \$23,000. These patients will benefit tremendously from the closing of the coverage gap and NPAF will monitor implementation of these provisions to ensure patient access is not compromised. Once again, because the Part D coverage gap is not a part of the rulemaking process and manufacturers have already signed contracts, to the extent PAF has data collected since 2004 documenting actual patient experience with Part D and to the extent to which data may inform decisions of change, NPAF will be involved in providing information to the agency in working to affect change. NPAF's role in offering prospective guidance will be limited to monitoring the effect of inevitable system glitches on the patient population.

Additional information about the closing of the Part D coverage gap can be found on the NPAF website by viewing the presentation by Marla Rothouse of CMS at the November 2010 NPAF Policy Consortium. Visit www.npaf.org to view the presentation.

Prevention and Wellness. The ACA includes important preventive care services provisions in health plans created after March 23, 2010 in an effort to ensure the long-term health of patients and lower health care expenditures. If a patient's plan is subject to these new requirements, the patient would not bear any cost-sharing responsibilities for these services, and would benefit from recommended screenings, vaccinations and counseling. The ACA also provides Medicare beneficiaries with a free annual wellness visit and eliminates Medicare coinsurance for certain preventive services.

The new annual wellness visit provides a personalized prevention plan. After careful consideration of the comments provided to CMS by the American Cancer Society Action Network (ACS CAN) to CMS on the annual wellness visit providing a personalized prevention plan visit, NPAF adopts ACS CAN's recommendations that in developing standards and guidance for the HRAs CMS should:

- 1) Clarify that the health risk assessment (HRA) is a statutorily required component of a personalized prevention plan visit even in the absence of detailed regulatory guidance and standards at this time.
- 2) Expedite the issuance of guidance and standards pertaining to the HRA so they coincide with the effective date of the new benefit – January 1, 2011.
- 3) Allow the rate of reimbursement for subsequent personalized prevention plan visits to vary based on the visit's complexity.
- 4) Modify the proposed list of elements to make some discretionary based on medical history or the results of the HRA and incorporate the HRA role's in addressing these elements as a prelude to the office visit providing a personalized prevention plan.

The document entitled, "Comments to the Proposed Rule for the Annual Wellness Visit Providing a Personalized Prevention Plan" describes the intent of the aforementioned recommendations as dispensing with a uniform "check-up" or "physical exam" designed to administer the same counseling and tests to all individuals to one that is "tailored to the patient's highest priority risks as determined, at least in part, by the HRA."

Together with the American Diabetes Association and the American Heart Association, ACS CAN submitted guidance regarding how best to integrate the HRA tool into the Personalized Prevention Plan. Essentially, the comments seek to assure the prominence and utility of the HRA by identifying

it as the primary tool for establishing/updating medical history and screening for certain risks. Thus, these groups have collectively recommended that the HRA should be:

- The key tool for guiding the visit with the healthcare provider, thus allowing the content of the appointment to be tailored to the needs of that particular patient based on their risk profile.
- Available/completed prior to a preventive medicine visit with health care provider.
- A robust enough questionnaire to uncover both health risks and disease symptoms, as well as the patient's demographic profile, that may reveal risks, health factors, and conditions amenable to intervention and modification once identified, such as diabetes, cancer, cardiovascular disease, and stroke.
- Coupled with written, personalized information in layman's terms outlining discovered risks and suggestions for risk modifications.
- Available in multiple formats from multiple vendors (i.e., do not require a single, standardized HRA) and available in the community, such as through State Health Insurance Assistance Programs (SHIP) that provide assistance to Medicare beneficiaries.
- Adequately reimbursed, taking into account the amount of time practices will need not only to analyze and interpret the HRA results, but also to provide various options for administering the assessment (e.g., some patients will be unable to complete a web-based HRA for various reasons and may need to complete a paper-based form in the office).

Because the above recommendations are consistent with NPAF's longstanding support of the use of primary, secondary and tertiary preventive services, NPAF adopts them in total. NPAF has already gone on record as working to successfully implement, and if possible, strengthen prevention and wellness provisions included in ACA. NPAF will carefully review the Center for Disease Control and Prevention's Health Risk Assessment guidance to be published in late March. A particular focus will be guidance language relative to care provided to those enrolled managed care.

Healthcare Workforce. It is estimated that by 2020, the health care workforce shortage will grow to 200,000 physicians and 1 million nurses.² Patients throughout the country will experience obstacles in accessing necessary health care services as a result of the shortage; those living in rural areas or underserved communities will be most vulnerable. Currently, the U.S. Bureau of Health Professionals estimates a shortage of approximately 400,000 nurses.³ Shortages in the number of doctors and nurses have led some states to consider expanding the authority of nurse practitioners and physician assistants in caring for patients. The Patient Protection and Affordable Care Act (ACA) recognized the health care workforce shortage in the U.S. and included several key provisions to help bolster the workforce and preserve access to providers for patients.

² Council on Graduate Medical Education, "16th Report: COGME physician workforce policy guidelines for the United States, 2000-2020" (2005). Richard A. Cooper and others, "Economic and Demographic Trends Signal an Impending Physician Shortage," *Health Affairs* 21 (1) (2002): 140-152. David I. Auerbach, Peter Buerhaus, and Douglas O. Staiger, "Better Later Than Never: Workforce Supply Implications of Later Entry into Nursing," *Health Affairs*, 26 (1) (2007): 178-185.

³ Bureau of Health Professionals, Health Resources Services Agency, "What is Behind HRSA's Projected Supply, Demand, and Shortage of Registered Nurses?" (2004).

A study by the American Society of Clinical Oncology (ASCO) in 2007 estimated a shortfall of up to 4,000 cancer doctors by 2020.⁴ In addition, the Oncology Nursing Society anticipates that a shortage in the number of oncology nurses will affect the quality of cancer care delivered in the U.S.⁵ Cancer is not only a disease which primarily affects older adults, but also the diagnosis for more than 70 percent of the patients served by Patient Advocate Foundation (PAF). The aging baby boomer population is directly linked to the anticipated shortage in oncologists, oncology nurses and oncology social workers.⁶

ACA permanently authorizes the federally qualified health centers (FQHC) and National Health Service Corps (NHSC) programs and increases funding for FQHCs and for the NHSC for fiscal years 2010-2015. The new law also establishes the National Health Care Workforce Commission in 2010 to coordinate federal workforce activities and make recommendations on workforce goals and policies and establishes the National Center for Health Workforce Analysis to undertake state and regional workforce data collection and analysis. Beginning July 1, 2010, ACA increases the number of Graduate Medical Education (GME) training positions by redistributing currently unused slots and promotes training in outpatient settings. Finally, ACA establishes Teaching Health Centers and provides payments for primary care residency programs in community-based ambulatory patient care centers; funding is appropriated for five years beginning in fiscal year 2011.

Since the healthcare workforce provisions included in ACA are dependent upon future appropriations, the impact of the provisions on the healthcare workforce shortage are unclear at this time. The provisions contemplate the utilization of the grant making process to address this challenge. NPAF is committed to working with Members of Congress and healthcare stakeholders to encourage fund appropriation to help strengthen our workforce and ensure patient access. NPAF is currently in consultation with policy advisors on collaborative activities to address tort reform and health workforce as significant inter-related pieces of the long-term SGR solution. NPAF will assure a coordinated, targeted strategic approach in its efforts to address politically-sensitive health workforce issues particularly as they relate to encouraging an expanded role and adequate reimbursement for non-physician practitioners with prescriptive ability, including, but not limited to, nurses, nurse practitioners and physician assistants. One particular area to consider is the provision of billing codes for these practitioners.

The “*Patient Protection and Affordable Care Act*” (ACA) included several critically important provisions to help strengthen the healthcare workforce. ACA provides new investments to increase the number of primary care practitioners, including doctors, nurses, nurse practitioners, and physician assistants. In addition, ACA establishes the National Health Care Workforce Commission to coordinate federal workforce activities and make recommendations on workforce goals and policies and also establishes the National Center for Health Workforce Analysis to undertake state and regional workforce data collection and analysis. NPAF hopes to assist the Commission by providing information garnered from patients served by PAF regarding gaps in the health care workforce. NPAF supports investments to strengthen our nation’s healthcare workforce in order to ensure patients have access to necessary providers. Insurance coverage absent adequate access to providers

⁴ American Society of Clinical Oncology. Forecasting the Supply of a Demand for Oncologists, March 2007.

⁵ The Impact of the National Nursing Shortage on Quality Cancer Care. Oncology Nursing Society, 2010.

⁶ C. Messner. Impending Oncology Social Worker Shortage?, Oncology Issues, September/October 2010.

will not help achieve meaningful access to healthcare for patients. NPAF also believes that Accountable Care Organizations (ACOs) discussed above can play a pivotal role as part of the solution to workforce issues by making the delivery of healthcare more efficient and assuring the best use of healthcare resources. To the extent that ACOs serve to pull down costs to the healthcare delivery system, those savings can be passed on to medical personnel providing the highest quality care.

Tier 2

- **Patient Protection and Affordable Care Act (ACA) Rules and Regulations**

Comparative Effectiveness Research

As an advocate for America's patient community, National Patient Advocate Foundation supports the development of research on the comparative clinical effectiveness of the multiple treatment options for those with chronic, debilitating and life-threatening conditions, in order to educate individuals on the options available, and to better equip them for the decisions they must make with their physicians regarding the best course of action in treatment. NPAF acknowledges that, in the cases of certain conditions and illnesses, there is a limited amount of evidence available on which treatments work best for which patients. These knowledge gaps have presented an opportunity for an expanded federal role in the study of the comparative clinical effectiveness of various medical interventions. NPAF supports the provisions included in the "*Patient Protection and Affordable Care Act*" (ACA) related to comparative effectiveness research (CER) and encourages stakeholders to make infrastructure development the top priority in the early stages of implementation.

Background. In weighing the options for an expanded federal role in the study of comparative effectiveness, we must define CER as applied in the health care sector. Comparative effectiveness research is broadly defined as the comparison of the various impacts of different options that are available for the prevention, detection and/or treatment of a given medical condition, for a particular set of patients. These studies might be comparisons of similar treatments, such as competing drugs indicated for the treatment of the same condition, or they may analyze different approaches to care, such as surgical intervention versus a less-invasive procedure, or pharmacotherapy. The analysis should focus on measuring the relative medical benefits and risks of a given treatment, inclusive of enhanced quality outcomes for the patient, to determine which patient populations would have the most to gain from a particular medical intervention. While some information regarding the effectiveness of a new drug, device or procedure is often publicly available, rigorous comparisons of the different treatments are far less common.

NPAF believes that all health care decisions should be informed by the best scientific and clinical evidence available. In order for patients to take responsibility for their health and become actively involved in informed decision-making with their personal physicians, they must be armed with the best available evidence regarding the condition and its methods of treatment. The Patient-Centered Outcomes Research Institute (PCORI), a national comparative clinical effectiveness research entity established in the new health care reform law has the potential to create a more centralized approach

to the coordination of research and its findings, to enhance the safety and quality of care, to improve clinical practice and delivery, and possibly lead to the genesis of new areas of research and scientific discovery.

Patient Needs and Personalized Care. It is of the utmost importance that this research be performed for the purpose of improving the quality, safety and delivery of care, **not to limit access, deny treatment or reimbursement.** While CE studies will help to inform health care decision-making, NPAF strongly urges that the findings should not over-look subpopulations that may benefit from a particular treatment, or neglect the needs of patients for whom the findings are not necessarily supportive which may include patients with multiple co-morbid, complex conditions. Physicians must have the latitude to define appropriate, personalized medicine. Health care decisions should continue to be tailored to fit an individual's needs, where CE research should inform, but not dictate, the patient's treatment options.

Organization and Funding. The Patient-Centered Outcomes Research Institute needs to be structured to ensure the highest level of accountability and credibility, while maintaining functional autonomy so that it may operate free from external political pressures. This Institute will coordinate research priorities, while allowing academic institutions and research centers throughout the country to perform reviews on a set of previously determined conditions and interventions. This process should eliminate inherent conflicts that may exist between the mission of existing federal agencies and that of a proposed independent entity.

Stakeholder Participation. The Board of Governors for the Institute will consist of all relevant stakeholders, including patient and consumer groups, representatives from the public and private sectors, such as government, physicians and other health care providers, medical specialists, insurers, and manufacturers of drugs and medical devices. It is essential that these stakeholders should be involved in every step of the process, from setting the research agenda, and developing study methodology, to the translation and dissemination of findings.

Scope, Selection and Prioritization of Research. Comparative effectiveness research should encompass all aspects of medical treatment, from standard methods of prevention, screening and diagnostic testing, to drug therapies, procedures and surgical interventions, to the use of medical devices. Focusing on the full spectrum of available approaches to care will encourage the ideal of a patient receiving the right care, at the right time, in the right setting enhancing quality outcomes.

Given the vast array of possible research topics, the earliest studies should be selected and prioritized by stakeholders including patients, providers, and researchers. Initial activities should be focused on conditions with significant impact on overall national health. For example, priorities might include the multitude of treatments for commonly occurring conditions such as obesity, heart disease, diabetes, or cancer. Research on these subjects is likely to have a wealth of information available for review. However, in these fields there may also be a great amount of confusion surrounding the relative benefits and risks of new technologies in comparison with the older standards of care.

Special patient populations, including minorities, should be integrated into comparative effectiveness research. NPAF is concerned that under our current system, the majority of clinical trials lack a balanced representation of minority populations who could be unduly burdened as a result of

decisions made through comparative effectiveness research that did not include data relative to clinical research for these populations. Comparative effectiveness guidelines should only apply to those populations that have been included in the research.

Chronic conditions are often associated with a disproportionate cost burden due to the extensive and prolonged course of treatment, while some conditions simply carry a higher price tag because of costly treatments required (e.g. radiation and chemotherapy). These areas deserve special attention from researchers when setting priorities, but once the research agenda has been established, **cost should not be used as a measurement in evaluating the comparative effectiveness of a product or procedure.** The prioritization of the research process is the only point at which NPAF believes cost should be taken into consideration.

Use of Research Findings. NPAF acknowledges that an inherent long-term goal behind the study of comparative effectiveness is to reduce overall expenditures on health care in the United States; however, we believe that it should only do so through the improved management of health care delivery e.g., by reducing waste and misuse, defining appropriate interventions and encouraging physician best practices. NPAF supports comparative effectiveness research inclusive of the collection of financial information i.e. cost effectiveness of a given treatment, in an effort to more fully inform patients of their out-of-pocket costs for treatment decisions being made between the treating physician and patient. Additionally, cost effectiveness information may be used to reflect broad disparities in cost of services from one region of the country to another allowing improved opportunity for stakeholders to more appropriately define treatment and coverage decisions. Comparative effectiveness research should inform patients and physicians as to what treatments offer the most benefits with the fewest relative risks, thus improving, not impeding, good clinical practice.

Transparency and Dissemination of Findings. In order to best serve payors, clinicians and patient populations, research findings should be translated in a manner suitable for their respective audience. Information should be summarized and described in detail as to inform medical professionals, but should also be made available in a clear manner to be easily managed by the average patient. The process should be transparent from beginning to end.

National Patient Advocate Foundation has created the NPAF Comparative Effectiveness Research (CER) Tracker, a compendium of the different CER studies being conducted in the United States. As these studies are completed, members of the NPAF Scientific Board of Directors will complete a review of the content, consistency and validity of the data used and will analyze the findings of the CER Tracker Project and suggest metrics for determining which projects are good and have scientific merit that will benefit our patients. The Scientific Board will thereby serve as “peer reviewers” for NPAF with regards to CER. The NPAF Scientific Board of Directors’ member composition is deliberately diverse so that it will present balanced views, and will have expertise between all of the members to capably evaluate any CER project set forth for review. The Scientific Advisory Board assists NPAF in evaluating projects NPAF may deem worthy. Going forward, the Scientific Board can help NPAF to review projects, and the organization can then set its metrics for worthiness, value, etc See www.npaf.org for biographies of scientific board members. The challenge facing NPAF in tracking and evaluating projects exemplifies the challenges of using CER for medically up-to-date national coverage decisions.

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Ultimately, the goal of the project is to initiate a standard process of review with members of a broad scientific community, coordinated with the NPAF/PAF Scientific Board of Directors, members of government agencies including NIH and establish this process as a peer-reviewed approach for each CER study.

Though the ACA has set in motion the new Institute, many details of its operation remain to be developed and implemented. NPAF will closely watch the ways in which the implementation of the new Institute's research agenda impacts patients.

- **Additional Regulations**

NPAF has a strong history in regulatory affairs and a positive reputation within federal health agencies. In addition to being very active in the implementation of ACA, NPAF will remain involved in regulatory affairs impacting patient access. NPAF will be engaged in the following additional non-ACA regulatory areas in 2011: physician fee schedule; hospital outpatient prospective payment system; hospital inpatient prospective payment system; risk evaluation and mitigation strategies (REMS); prescription drug user fee act reauthorization (PDUFA); health information technology; and others.

Health Information Technology

The "*American Recovery and Reinvestment Act of 2009*" (ARRA) was signed into law in February 2009 and included \$20 billion to encourage the adoption of health information technology (HIT) and assist in the development of a robust HIT infrastructure. The law provides \$17.2 billion in Medicare and Medicaid incentives from 2011 to 2015 to assist providers and institutions in adoption HIT. In order to receive incentive payments, adopters must demonstrate "meaningful use" of electronic health record (EHR) technology. Beginning in 2015, providers will receive negative payment updates if they are not "meaningful users."

National Patient Advocate Foundation supports the rapid deployment of health information technology (IT) and wishes to ensure that patient concerns including privacy and security safeguards are considered in the development of health IT policy, standards and innovations. Health IT remains a critical issue relative to both health care access and quality. NPAF supports widespread adoption and use of health IT to help reduce the nearly 100,000 deaths that occur each year due to medical errors. The U.S. Department of Health and Human Services has estimated that adoption of health IT could reduce health spending by as much as 30 percent annually. In addition, health IT would improve the quality of care, reduce duplication, and increase medical efficiency for patients.

As a member of the Health IT Now! Coalition, which unites patients, practitioners and employers, NPAF supports federal efforts including those that are part of ARRA to promote a connected health IT system. NPAF supports the following Coalition principles:

- Create a public-private process to establish HIT standards;
- Offer Federal grants, subsidies, reimbursement to physicians and hospitals to adopt HIT through a balanced process that affords equal opportunities to smaller and community hospitals and providers;
- Provide and promote patient education to encourage the use of HIT; and
- Establish Federal and State roles to resolve HIT issues.

E-prescribing. An issue related to HIT, is e-prescribing, which NPAF believes is cost-effective, provides immediate access to information, improves medication management and provides for safer care. NPAF supported language included in the *“Medicare Improvements for Patients and Providers Act of 2008”* (MIPPA) which mandated e-prescribing under Medicare and encourages further adoption of e-prescribing for non-Medicare providers. Again, NPAF would like to emphasize the importance of positive incentives for providers, especially those serving underserved and high-risk populations, who may struggle to adopt this system.

Collaboration with Patients in the Development of Health IT. It is critical that the consumer/patient voice be considered and heard as health IT innovations are developed and that this perspective is integral to the development of national policy. NPAF will continue to represent patients as part of the Health IT Now! Coalition to ensure that this perspective is integral to the development of national policy. Additionally, NPAF will continue to urge patient appointments to committees directing these efforts in the government and private sector.

Interoperability. It is important to develop a national health IT framework that will be interoperable throughout the country so that hospitals, clinics, doctors, public agencies, and other entities are not each investing in creating redundant systems that are unable to communicate effectively with other systems. Under ARRA, the Office of the National Coordinator (ONC) is responsible for endorsing certification and standards for electronic health records. National Patient Advocate Foundation will closely monitor this critical issue to ensure patients benefit from adoption of HIT. In addition, HIT systems must be affordable, devoid of redundancy and must address gaps in the continuum of health care delivery. Health savings would also result from accurate, portable patient records that would reduce the number of repeated tests and procedures. Electronic medical records, personal health records, e-prescribing and other IT tools could also result in quality improvements based on a reduction of secondary adverse reactions and medical errors resulting from contraindicated drugs, treatments or therapies or unclear handwritten prescriptions or records. These IT tools must be certified, work well, not be burdensome, and serve as a resource that adds to efficiency to incent utilization.

Decision Assist Tools. Health care practices and facilities throughout the country are adopting decision assist tools, some of which are web-based, to assist physicians when diagnosing patients. While the vast majority of diagnoses are reached through the experience and knowledge of the treating physician, an estimate 10 to 15 percent of patient cases are more difficult to determine and decision assist tools and checklists will help accelerate the diagnosis process and promote quality care and patient safety. NPAF strongly supports the integration of decision assist tools into health IT systems.

Tier 3

Development of Pathway for Follow-on Biologics

Where We Stand. National Patient Advocate Foundation actively supports efforts to protect patient safety and increase patient access to effective low-cost biotechnology therapeutics. Patient safety should stand at the center of a regulatory approval pathway for follow-on biologics.

Background. *Chemical drugs* are typically made by mixing together well-defined chemicals in controllable “recipes” following the formulas and the predictable rules of organic chemistry. The same final product can sometimes be obtained through a very different process, and the product can be analyzed in a laboratory to confirm that it is exactly what it is supposed to be. It is a relatively straightforward exercise to show that a generic chemical product is the same as a branded product. Evidence from clinical trials is not necessary, and cannot be submitted in an application for a generic product.

Biologics are more complex molecules than chemical drugs; they are not manufactured through chemical synthesis but instead are made by genetically engineering living cells to become miniature factories producing the desired molecules (proteins). These living cells are inherently variable and susceptible to slight changes in their environment that can significantly alter the proteins they are engineered to produce. Because no two living cell lines are identical, no two biologics manufacturing processes have identical starting materials or proceed in the same way. A follow-on biologic manufacturer that uses different starting materials and a different process will produce a product that is different from the innovative product. In addition, the complexity of biologics currently makes it impossible to show in the laboratory that a follow-on biological product will work the same as the innovator in patients. The effects of the difference between a follow-on biologic and its respective innovator product can only be determined by subjecting the follow-on to substantial clinical testing in patients to prove that it is safe and effective.

Because of the complex science involved, the Food and Drug Administration (FDA) has indicated that the generic drug approval pathway is not appropriate for complex biologics. The healthcare reform law includes provisions establishing an approval pathway for follow-on biologics.

NPAF recommends that regulatory agencies recognize and adopt the following principles as they implement a regulatory pathway for follow-on biologics:

- **Patient Safety.** Patients should not have to accept greater risks or uncertainties in using a follow-on product than an innovator’s product. Thus FDA should:
 - Ensure that approval of pioneer biotechnology products is based on rigorous standards of safety, purity and potency. Recognize that clinical trial evidence and data are fundamental for evaluating and demonstrating safety and effectiveness of a follow-on biologic, and must be required for all biosimilars
- **Maintain the Physician-Patient Relationship.** Small molecule generic drugs can be designated as therapeutically equivalent and may be dispensed interchangeably with

innovator products without physician knowledge. However, this interchangeability should not apply to generic substitutions and auto-substitutions. The current state of science is not sufficient to establish interchangeability for complex follow-on biologics. Accordingly, FDA should assure that patients are not given follow-on biologics unless expressly prescribed by a treating physician and dispensed as written.

- **Preserve Incentives for Innovation.** NPAF supported the inclusion of substantial non-patent data exclusivity as part of the new pathway for follow-on biologics in order to preserve incentives for the research, development and manufacturing of new innovative therapies, as well as new indications for biologic products.

Follow-on manufacturers should not be able to rely on FDA's prior approval of pioneer biologics to support approval of their own products. Such data exclusivity is necessary because a follow-on biologic may be similar enough to a pioneer biologic for regulatory purposes, but different enough to avoid the innovators' patent. Thus non-patent exclusivity is necessary to maintain effective market protection. Further, the biologics industry maintains heavy dependence on access to significant amounts of high cost public-private investment capital, and high risks and costs involved in the development of new biologic medicines all warrant a substantial period of exclusivity.

Continue to Prioritize FDA Review and Approval of New Therapies and Cures. Any applications for approval of follow-on biologics will raise novel and complex questions of science and law, requiring substantial time and additional resources to ensure a thorough regulatory review for safety, purity and potency. In order to avoid slowing down FDA's review and approval of new therapies and cures, Congress must ensure that workload associated with these new applications does not harm FDA's ability to efficiently review new drugs and biologics, and new treatments continue to have the highest review priority.

Biopharmaceutical innovation can provide major improvement with respect to the quality and length of human life but could also exacerbate cost pressures and access disparities in health care. NPAF strongly urges Congress and the FDA to balance the objectives of innovation incentives and price competition as well as ensure patient safety and will monitor and comment upon the implementation of follow-on biologics legislation within that context. It will also pay close attention to assure competing biologics have effects which are biologically equivalent. NPAF will assure board members remain updated on this complex topic by disseminating important information and providing topical experts at board meetings in 2011.

Value-Based Purchasing

Background. "Value-based purchasing" is a term used to describe a health care provider reimbursement methodology that integrates provider performance and payment incentives into reimbursement and fee-schedule determinations. Under value-based purchasing policies, reimbursement rates are determined based on providers' performance as evaluated pursuant to quality-related standards, as laid out by plans, to meet pre-established targets for delivery of a wide range of health care services. This payment model seeks to reward physicians, hospitals and other providers for meeting certain measures of quality and efficiency for medical care they provide.

Quality Improvements. National Patient Advocate Foundation favors value-based purchasing methodologies designed to offer incentives for the delivery of high-quality care, rather than penalizing those services that do not meet the prescribed standards. However, NPAF does recognize that “never-events” are an exception in a value-based system. Provider reimbursement should not be reduced under a value-based purchasing system; physicians, for example, should not be dropped from a plan because they provide more costly services to patients in relation to other providers. Payment reductions based on performance evaluation would make services even more inaccessible for patients, as disincentives may reduce the availability of eligible providers. In contrast, we believe that incentives that encourage improved quality of care delivered would be a benefit to both patients and providers. We therefore recommend that these reimbursement systems be compensatory in nature, not punitive.

Patient Access. As this payment methodology becomes more prevalent, NPAF will seek to ensure that the needs of patients are addressed. NPAF believes that implementation of a value-based purchasing system of quality measures would support both improvements to beneficiaries’ quality of care, as well as the implementation of appropriate reimbursement updates, but must be structured to provide incentives for high-quality care. For instance, payments should not be directly linked to outcome improvements, as this may negatively impact a physician’s willingness to treat high-risk patients or those with inevitable or irreversible outcomes. As value-based purchasing models develop, it is imperative that patient access to quality care be facilitated and that standards of quality outcomes reflect the latitude of changes in disease status that contribute to debilitation even with quality care.

Need for Adequate Reimbursement. As an advocate for America’s patient community, NPAF recognizes that adequate reimbursement for professional services is an essential component to ensuring patient access to care. NPAF also recognizes the need for maintaining strict safeguards to protect the safety and well-being of health care consumers. Implementing performance-based programs may contribute to appropriate reimbursement standards and may likely advance the safety and quality of care and its delivery.

Development of Performance Standards and Stakeholder Participation. A number of parties within the health care sector support the use of incentive programs to improve the quality of health care, however some have expressed concerns with the development and legitimacy of quality indicators, increased administrative burdens, physician autonomy and the rights and privacy of patients. Therefore, NPAF urges policymakers to include all stakeholders in a collaborative process to develop appropriate evaluation standards. We also urge that standardized and consistent quality-related measures be developed and adopted by all stakeholders to ensure the programs’ integrity and maintain the best interests of the patient population. We also note the importance of developing distinct standards to evaluate performance relative to our most vulnerable patient populations including: Medicare beneficiaries; disabled; and those suffering from chronic, debilitating and/or life-threatening illnesses.

Quality Indicators and Standards. As noted above, standardized and consistent quality-related measures are critical if value-based purchasing programs are to meet the intended goal of improving the quality of care. A system that evaluates performance as it relates to cost, volume or efficiency is all too often contrary to patient needs and access to quality care. Policymakers must carefully consider how “quality of care” will be defined, measured and evaluated including a process to assure

attention to the management of pain, nausea, and mobility. Patients define independent living as a primary goal in disease management and the primary standard for defining quality. It is important to recognize that the term “quality indicator” could be used to describe indicators that result in determinations that overly expensive care has been provided, as well as indicators that result in determinations that the provided care could be harmful to the patient’s well-being. These two concepts are quite different and must be addressed prior to implementation.

Data Collection and Reporting Costs. NPAF is concerned that the collection of such data should not be overly time-consuming, resource-intensive, expensive, duplicative or otherwise burdensome so as to discourage provider participation. We recognize also that the cost of compliance and participation is likely to include information system or software investments as well. It is important that provisions be established for incenting or subsidizing physicians in obtaining the technology needed to participate in a value-based purchasing program. We also encourage that data collection requirements be developed in consideration of the variable accessibility of different types of data and recognize, for example, that administrative or claims data may be easier to collect and report than encounter data. NPAF supports the development and use of interoperable electronic health infrastructures that will facilitate collection, transmittal and evaluation of performance-related data without creating a financial or labor burden for providers, which, subsequently, would threaten patient access to care through diminished resources and professional staff.

Patient Choice. Finally, NPAF recommends that the performance ratings for each provider measured across all payor types be made available publicly in order to ensure transparency and assist patients in selecting a provider. Patients make the greatest investment in any healthcare transaction and ultimately it is the patient who entrusts their life to physicians. A system of informing the public of physician performance ratings will encourage utilization of those most qualified physicians and will hopefully lead to more qualified physicians.

2011 State Legislative Priorities

Tier 1

- **Tracking of state Medicaid budgets with appropriate intervention when changes are noted**

Background: Medicaid patients represented 10.6% of all new patient cases to PAF in 2009, which is consistent with figures from previous years.

Medicaid spending for fiscal year (FY) 2010 is estimated to exceed \$353.8 billion, an increase of 8.2 percent over FY 2009, according to National Association of State Budget Officers (NASBO) *2009 State Expenditure Report*. State funds decreased by 1.0 percent while federal funds increased by 14.4 percent over FY 2009 amounts. In fiscal year 2010, Medicaid is estimated to account for 21.8 percent of total spending, the single largest portion of total state spending which would exceed elementary and secondary education as a percent of total state spending.

The large increase in federal funds can be attributed to the enactment of the *American Recovery and Reinvestment Act of 2009* (ARRA) which provides a temporary increase in the Federal Medicaid Assistance Percentage (FMAP) in order to allow individuals to maintain health care services during the recession. Under ARRA, all states receive a temporary increase in their FMAP as well as additional amounts for those states facing the highest unemployment rates. In order to receive the federal funds, maintenance of effort requirements (MOE) includes not having more restrictive standards, methodologies and procedures in place than were in place July 1, 2008. The downturn in the economy has resulted in significant increases in Medicaid enrollment as it has in previous economic slowdowns. Enrollment growth averaged 8.5 percent in fiscal year 2010 with states projecting Medicaid enrollment to grow by 6.1 percent in fiscal 2011.⁷

Nearly every state has implemented at least one new Medicaid policy to control spending in fiscal 2010 and fiscal 2011 with more states turning to provider cuts more than any other area, according to the Kaiser Commission on Medicaid and the Uninsured's 2010 annual survey. This concerns National Patient Advocate Foundation (NPAF) as it has the potential to drive providers away from accepting Medicaid patients and restrict access to patients who do not have provider alternatives, or the means to seek them.

Medicaid provider rates are linked to economic conditions and under budget pressure states are often forced to reduce rates until economic conditions improve. Based on the Kaiser Commission survey, 39 states in fiscal 2010 implemented a provider rate cut or freeze compared to 33 states in fiscal 2009. In fiscal 2011, 37 states have planned provider rate restrictions. In addition, 14 states have planned benefit restrictions in fiscal 2011 which include the elimination of covered benefits as

⁷ Henry J. Kaiser Family Foundation. Kaiser Commission on Medicaid and the Uninsured's 2010 annual survey. October, 2010.

well as the application of utilization controls or limits for existing benefits. Examples include the recently proposed 6.3% across-the-board budget cuts for Medicaid proposed in Washington State. Medicaid spending, similar to the health care spending is projected to increase faster than the economy as a whole. With Medicaid comprising over 21 percent of state budgets, these long-term growth rates will continue to strain state budgets.

Under the *Patient Protection and Affordable Care Act* (ACA), enacted in March 2010, Medicaid programs will be expanded to cover non-pregnant, nonelderly individuals with income up to 133 percent federal poverty level beginning in January 1, 2014. The cost for those newly eligible for coverage will be fully federally funded in calendar years 2014, 2015, and 2016 with federal financing phasing down to 90 percent by 2020. The ACA imposes a maintenance-of-effort (MOE) requirement on eligibility standards, methodologies, and procedures for adults until the new insurance exchanges are fully operational in 2014, and for children in Medicaid and CHIP through 2019. There is a limited exception during the period January 1, 2011 through December 31, 2013 for a state that certifies it has a budget deficit on or after December 31, 2010.

While the major expansions to cover the uninsured will not be implemented until January 1, 2014, other changes under health care reform may affect states more immediately including: the maintenance-of-effort provisions for Medicaid and CHIP, a new option to cover childless adults in Medicaid using the regular Medicaid match, changes to drug rebates under the Medicaid program, new long-term care options for community based care, the establishment of temporary high risk pools in each state until the exchanges are operational, and changes in the insurance market in every state.

- **Assisting in the implementation of high risk pools at the state level**

Background: As highlighted in the Federal Legislative priorities section, NPAF is concerned that the budget allocated for the establishment and/or expansion of high risk pools may not be sufficient through January 1, 2014. NPAF is assessing the need for legislation to address these concerns with the temporary high-risk pools created by the health care reform law. The State Government Affairs team is monitoring the activity at the state level.

The high risk pool plans, also known PCIPs (Pre-existing Condition Insurance Plans), vary from state to state. As part of the *Patient Protection and Affordable Care Act* legislation, states were given the option of running their own program or letting the federal government do so and had to inform the Department of Health and Human Services (HHS) by July 1, 2010. Twenty-seven states opted to administer their own plans while the remainder has left it up to the federal government to administer these plans. Enrollment has been lower than expected in both state and federally administered plans; enrollment as of November 2010 has been less than 8,000 individuals nationwide, when initial estimates by the congressional budget office put the number of enrollees at 200,000 by 2013. As a result, HHS has lowered premiums in November by approximately 20% in an attempt to spur participation

One of the stumbling blocks for enrollment remains the waiting period of up to 6 months before patients with pre-existing conditions can join. Various states have proposed solutions to this waiting period dilemma, including exceptions for patients with cancer and HIV. The NPAF State Government Affairs team will be not only monitoring the implementation of state high risk pools, but is prepared to assist with state legislative and regulatory efforts to make these pools successful. As noted above, NPAF will explore initiatives that might help boost enrollment and will lead efforts to advocate for changes that will make enrollment increase. This is an important priority as it is directly correlated to access to care challenges for those with pre-existing conditions and is characterized by strong bipartisan support.

Tier 2

- **Oral chemotherapy parity legislation**

Background: Parity in the reimbursement for orally administered chemotherapy vs. IV administered chemotherapy remains an issue which the NPAF State Government Affairs team will monitor on a state by state level. There is growing pharmacoeconomic data to show that oral chemotherapy regimens have both a cost effective and clinical efficacy advantage over same-compound and established I.V. regimens.⁸⁹¹⁰¹¹¹²¹³

While efforts are being made to construct legislation at the federal level with H.R. 2366, introduced in 2009 by Representative Brian Higgins (D-NY-27), this bill is currently at an impasse in the House Education and Labor Subcommittee on Health, Employment, Labor, and Pensions. Eleven States and the District of Columbia have passed oral chemotherapy parity legislation, with similar bills introduced in 16 other states. The latest state to pass such legislation was Connecticut in May, 2010. In California, Senator Roderick Wright (D, S-25) had introduced legislation (SB961) in 2010 that passed both the General Assembly and Senate and was subsequently vetoed by the Governor in September, 2010. Sen. Wright has stated he intends to re-introduce this bill in 2011 and the climate has significantly changed with the election of Jerry Brown as Governor and the likelihood of the same bill passing in California in 2011 is considerably higher.

⁸ Galewitz, P. Kaiser Health News. Henry J. Kaiser Family Foundation. November 5, 2010.

⁹ Best JH, Garrison LP. Economic evaluation of capecitabine as adjuvant or metastatic therapy in colorectal cancer. *Expert Rev Pharmacoeconomic Outcomes Res.* 2010 Apr; 10(2):103-14.

¹⁰ Bradbury, PA, Tu, D, et. al. Economic Analysis: Randomized Placebo controlled Clinical Trial of Erlotinib in Advanced Non-Small Cell Lung cancer. *JNCI.* Mar 2010 (102-5): 298-306.

¹¹ Sargent DJ, for the Adjuvant Colon Cancer Endpoints (ACCENT) Group. Time dependent patterns of failure and treatment benefit from adjuvant therapy for resectable colon cancer. Lessons from the 20,800 patient ACCENT dataset. *Proc Am Soc Clin Oncol.* 2007; 25:165s. Abstract 4008.

¹² O'Connell MJ, for the Adjuvant Colon Cancer Endpoints (ACCENT) Group. Survival following recurrence in patients with adjuvant colon cancer: findings from the 20,800 patient ACCENT dataset. *Proc Am Soc Clin Oncol.* 2007; 25:165s. Abstract 4009.

¹³ Twelves C, Wong A, Nowacki MP, et al. Capecitabine as adjuvant treatment for stage III colon cancer. *N Engl J Med.* 2005; 352:2696-2704.

The NPAF State Government Affairs team will monitor those states where there is a high probability of the legislation passing in 2011 and deploy our resources accordingly. These states are: Arizona, California, Georgia, Illinois, Michigan, New York, Pennsylvania and South Carolina. NPAF will utilize its grass-roots volunteer organization to effectively monitor the legislation in these states in order to appropriately allocate its bi-partisan lobbying efforts.

Tier 3

- **Expand use of compendium to a minimum of 2-3 per state**

Background: A compendium is a comprehensive listing of FDA-approved drugs and biologics. It is the guide by which providers make clinical decisions re treatment. State programs are currently required by law to cover off-label use of anticancer drugs if they are listed as active drugs in one of the accepted pharmaceutical compendia or the peer-reviewed literature. The four CMS-recognized compendia as of September 2010 include: The American Hospital Formulary Service *Drug Information*[®] (*AHFS-DI*[®]); Thomson Reuters *DrugDex*[®]; the National Comprehensive Cancer Network (NCCN) *Drugs & Biologics Compendium*[™]; and Gold Standard/Elsevier's *Clinical Pharmacology*.¹⁴

NPAF is concerned that several states are utilizing single drug compendiums in their decision making processes. If only one compendium is recognized it frustrates the pre-authorization process. NPAF believes it is to the best advantage of patients that states utilize at least three compendia. NPAF will work to stay abreast of national activity and raise awareness of this issue through correspondence and the publication of position statements on the subject in order to effect legislation at the state level. In addition, NPAF will collaborate with other healthcare stakeholders at the state level to bring attention to this important issue and seek positive resolution for patients.

Conclusion

The 2011 Policy Agenda of National Patient Advocate Foundation is informed by the Directors who serve on the Policy Committee of the National Patient Advocate Foundation Executive Board of Directors in collaboration with the professional policy staff of National Patient Advocate Foundation, their consultants and the professional case management staff of the Mission Delivery division of Patient Advocate Foundation. The Mission Delivery division provides specific data documenting patient access experiences throughout the nation that define specific trends of newly emerging issues and track early warning signals of access issues that may be contrary to legislative and/or regulatory guidance.

Through these collaborations, the priorities are established identifying the Tier I, II and III issues in the areas of Federal Legislative, Federal Regulatory and State Government Affairs. It is through our partnerships and collaborations with diverse non-profit patient organizations, health care stakeholders across the continuum from prevention to research to clinical intervention, survivorship and wellness communities that NPAF will advance each of these initiatives. These partnerships and collaborations with both elected and appointed

¹⁴ US Department of Health and Human Services: Center for Medicare and Medicaid Services, 2010.

government officials at the state and federal levels will inform each of the primary areas of focus in order to effect improvements in health care access for all people in America.

Support of these published priorities may lend more ready adoption of the recommended improvements cited throughout the narrative. NPAF welcomes outreach and extends a standing invitation to organizations to work with NPAF state volunteers, state policy liaisons and government affairs professionals to mutually address each of the opportunities presented herein.

This document can be referenced at www.npaf.org.

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cc: Rene Cabral Daniels, Chief of Staff

Addendum

Submission dates for Commissions, Committees etc.

January 2011

1) COMMITTEE TO REVIEW ADMINISTRATIVE STANDARDS

The NCVHS anticipates a notice will be filed in the Federal Register later this year. Interested parties do not have to wait for the Federal Register notice, but may submit a nomination now.

2) INDEPENDENT PAYMENT ADVISORY BOARD

The legislation is silent with regard to when the President shall appoint the Board's members, but the board is to begin issuing recommendations in January 2014, its members require Senate confirmation, and the Board begins receiving appropriations in FY 2012 (October 1, 2011- September 30, 2012). Consequently, it would seem logical that the Board's appointments would come no later than sometime in 2011.

3) CONSUMER ADVISORY COUNCIL TO THE INDEPENDENT PAYMENT ADVISORY BOARD

The Comptroller General's office says they are not gearing up for the appointments to the Council for a while and do not anticipate doing so until 2011.

4) ADVISORY GROUP ON PREVENTION, HEALTH PROMOTION, AND INTEGRATIVE AND PUBLIC HEALTH

The Surgeon General's office says the process for appointing the Advisory Group is under discussion, but no details have been finalized or made public. A notice was filed in the Federal Register on July 1, 2010, but gave no details about the process and when nominations are due.

5) BOARD OF TRUSTEES OF THE CLASS INDEPENDENCE FUND

Ann Widger at HHS told me that even where the Administration has not yet filed a formal notice in the Federal Register we should not wait but go ahead and send nominations/resumes now.

6) CURES ACCELERATION NETWORK (CAN) REVIEW BOARD

The law authorizes an appropriation of \$500 million for FY 10 (October 1, 2009 - September 30, 2010). Though there has been no notice yet in the Federal Register, Ann Widger at HHS told me that even where the Administration has not yet filed a formal notice in the Federal Register we should not wait but go ahead and send nominations/resumes now.

7) MULTI-STAKEHOLDER GROUP INPUT FOR QUALITY MEASUREMENT

It would seem necessary that the groups be up and running in 2011.