

# policy impact

CSL Behring Public Policy Newsletter Spring 2011

## Specialty Tier Legislation: Protecting Patient Access

*Study after study shows that many diseases requiring high-cost care have the potential to destroy a family's financial solvency or threaten their ability to take a necessary medication.*

Specialty tier (or tier 4) structures in health plans create such scenarios for individuals with chronic conditions. While patients should strive to be prudent purchasers in the health care marketplace, specialty tiers are viewed by many as contrary to the original purpose of health insurance, which is the spreading of costs amongst both the healthy and the ill.

### Tiers



New York became the first state in the nation to enact legislation prohibiting commercial health plans from creating specialty tiers. A number of states in 2011 have had legislation introduced that would either prohibit or limit this practice.

According to Dominick Spatafora, President of the Neuropathy Action Foundation, a leading patient advocacy group, "This type of legislation is very important for people who suffer from chronic illnesses. Insurers are abandoning the traditional arrangement that has patients paying a fixed amount, like \$10, \$20 or \$30 co-pay for a prescription, and instead are charging patients a percentage of the cost of certain high-priced drugs, usually 20 to 33 percent for Tier 4. These costs can amount to thousands of dollars a month and limit access to vital, life-saving medications."

### Specialty Tier Background

In response to increasing costs, many health plans and prescription drug plans have instituted a tiered payment system for medications. These tiers are often labeled as follows:

**Tier 4** Specialty: Percentage of drug cost co-pay

**Tier 3** Non-preferred: Highest co-payment

**Tier 2** Preferred: Higher co-payment

**Tier 1** Generic: Lowest co-payment

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### CSL Behring Public Affairs

*CSL Behring is committed to educating decision-makers and impacting public policies that affect patient access to care. The company has an active public affairs group in the United States including Dennis Jackman, Sr. Vice President for Public Affairs; Patrick Collins, Director, Public Affairs; Kim Isenberg, Sr. Manager, State Government Affairs; and Ryan Faden, Manager, State Government Affairs. All four have extensive public policy backgrounds and work closely with affected stakeholders and political thought leaders to affect change. Please contact them with any questions you may have regarding public policy issues.*

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Many plans now include a fourth, 'specialty tier' and require enrollees to pay a percentage of the cost (co-insurance) of the most expensive medications as opposed to a fixed co-pay amount. Biologic medications are increasingly being placed on the specialty tier. This regressive cost-sharing structure places a significant disproportionate financial burden on people with chronic illness. Such arrangements have the potential to stop patients from filling their prescriptions since they are unable to afford them.

The emergence of co-insurance for prescription drugs is an increasing trend. Specifically, the Kaiser Family Foundation recently reported that in 2009, over three-quarters (78%) of those with employer sponsored prescription drug coverage were in plans with four tiers. Conversely, nine years earlier in 2000, only 27% of workers with prescription drug coverage had a plan with four tiers of coverage. It should be noted that this problem will not be solved through the implementation of federal health care reform.

**Specialty Tiers and Health Care Reform**

While the Patient Protection and Affordable Care Act (PPACA) will reform many aspects of health care, it does not specifically regulate prescription drug health insurance coverage. Rather, its provisions provide the following:

- Require that prescription drug benefits be an "essential benefit" in health plans sold or renewed in 2014 and beyond,
- Prohibit lifetime caps on benefits from September 2010 and beyond, including for prescription drugs,
- Prohibit annual caps on insurance benefits in 2014 and beyond, including for prescription drugs.

Accordingly, even with PPACA, limited authority exists to avert trends toward increased cost sharing, co-insurance and specialty tiers. In fact other provisions contained within PPACA, including additional review of premium increases and requirements for spending a certain amount of premium dollars on health care delivery rather than

administrative costs may actually raise the potential for increases in cost-sharing. Legislation to restrict specialty tiers is one approach being employed to help ensure that every person living with chronic illnesses has access to the therapies that can slow disease progression and increase their quality of life, albeit at a potentially very costly financial impact for the individual in the specialty tier.

*ryan.faden@cslbehring.com      kim.isenberg@cslbehring.com*

**Six LEAD Grants Nearing \$100,000 Awarded to Patient Organizations**

*Deadline for next round of grant submissions is April 30, 2011*

CSL Behring has awarded advocacy grants totaling almost \$100,000 to six patient organizations through its Local Empowerment for Advocacy Development (LEAD) program. LEAD grants support the grassroots advocacy efforts of organizations committed to helping people who use plasma-derived or recombinant therapies to manage rare and serious diseases.

"CSL Behring is pleased to recognize and support these organization's advocacy efforts, all of which play a vital role in expanding patient access to information and healthcare," said Dennis Jackman, Senior Vice President, Public Affairs, CSL Behring. "We hope these grants will help improve the lives of people with bleeding disorders, immune deficiencies and hereditary angioedema." The following organizations were recently awarded CSL Behring LEAD grants:

**The Hereditary Angioedema Association (HAEA)**

The HAEA will use its LEAD grant to support the establishment of a public policy program. Already, the HAEA

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## Six LEAD Grants Nearing \$100,000 Awarded to Patient Organizations

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held its first federal advocacy day where select volunteers traveled to Washington to inform their legislators about hereditary angioedema and the need for increased research into this potentially life-threatening condition.

"The Association is passionate about making a better life for all HAE patients and is grateful for the opportunity to advocate for HAE research on a federal level," said Janet F. Long, Executive Vice President of the HAEA.

### The Hemophilia Foundation of Maryland (HFM)



HFM received a LEAD grant from CSL Behring to support its legislative initiatives for a Maryland Bleeding Disorders Standards of Care. The

Foundation is looking to build upon its success from the previous legislative session when the bill was introduced.

"In 2010 our small but proactive bleeding disorders community championed the introduction the Hemophilia Standards of Care Act (Health Insurance Coverage for the Treatment of Bleeding Disorders)," said Executive Director Emma Miller-Clark. "The LEAD grant will enable us to pick up where we left off in 2010 and provide funding to continue HFM Maryland Days and educate future advocates."

### The Immune Deficiency Foundation (IDF)



IDF will use its LEAD grant to support their annual Capitol Hill Day where

individuals with primary immune deficiencies and their families travel to Washington, D.C. to meet with their legislators and discuss issues impacting this community. In addition to Capitol Hill Day, the IDF will also jointly conduct a *Raise Your Voice!* program with CSL Behring. *Raise Your Voice!* is an initiative that assists teenagers and young adults in becoming active advocates and is also part of the CSL Behring LEAD program.

"The IDF thanks CSL Behring for the LEAD grant and for letting the voices of those with primary immunodeficiencies be heard," said Lawrence A. LaMotte, Director of Public Policy at IDF.

### The New England Hemophilia Association (NEHA)



NEHA will use the grant from CSL Behring to expand its consumer network and to train volunteers. In addition, the LEAD grant will provide staffing resources to help drive NEHA's advocacy priorities through legislation and coalition building.

"NEHA is grateful to receive a LEAD grant from CSL Behring in support of our Advocacy program. Promoting the needs of the bleeding disorders community in our six-state area presents many challenges. We look forward to working with CSL Behring to serve our community," said Kevin R. Sorge, Executive Director of NEHA.

### The Midwest Hemophilia Association (MHA)



MHA will use its LEAD grant to bolster legislative efforts in support of passage of Standards of Care for People with Bleeding

Disorders in Missouri. In addition, MHA will start grass-roots advocacy in Kansas and also help educate the public about women's bleeding disorders.

"MHA is delighted to receive this generous LEAD grant from CSL Behring. This grant will help our ultimate goal to make all our members better self-advocates," Kristin Marema, MHA Board Member, said.

### The Bleeding Disorders Foundation of Washington (BDFW)



LEAD grant funds to BDFW will be used to support its state advocacy day in Olympia, WA and to increase participation from the eastern part of the state.

"The Foundation is thrilled to be awarded a CSL Behring LEAD Grant". Kristian Prill, Executive Director said. "The funding being provided will allow us to increase education and advocacy for bleeding disorders and healthcare reform at a critical time in the process."

*patrick.collins@cslbehring.com*

## Federal Judges Split 3-2 in Health Care Law Rulings

*Three judges ruled in favor of health care legality while two others found the individual mandate illegal. The US House voted to repeal the law while the US Senate rejected efforts to repeal.*



*Federal District Court Judge Roger Vinson who ruled the health care reform legislation to be unconstitutional in its entirety.*

To date, there have been five separate rulings in U.S. district court specific to the health care law (named the Patient Protection and Affordable Care Act) which was passed by the last session of Congress in March 2010.

Easily the most controversial ruling came on January 31, 2011 when federal district court judge Roger Vinson of Florida ruled that the individual mandate requirement that all individuals be required to have some form of health insurance is unconstitutional. However,

Judge Vinson's ruling goes beyond that of fellow federal district court judge Judge Henry Hudson who also found the individual mandate to be unconstitutional. Judge Vinson struck down the entire healthcare reform law, ruling that the requirement for individuals to purchase insurance is unconstitutional and is too central to making the law function. Further, he said the whole law cannot stand because the law depends on the mandate to work. In his opinion, Judge Vinson wrote, "I must conclude that the individual mandate and the remaining provisions are all inextricably bound together in purpose and must stand or fall as a single unit."

Judge Vinson further wrote that Congress does not have the power to compel an individual to purchase insurance. Under the reform law, an individual must buy health coverage by 2014 or face a penalty. "To now hold that

Congress may regulate the so-called 'economic decision' to not purchase a product or service in anticipation of future consumption is a 'bridge too far.'" Vinson wrote. "It is without logical limitation and far exceeds the existing legal boundaries established by Supreme Court precedent."

The lawsuit, filed by 26 states and the National Federation of Independent Business, has been the most visible among legal challenges to the reform law. Dozens of Republican lawmakers, including House Speaker John Boehner (OH) and Senate Minority Leader Mitch McConnell (KY), filed court briefs opposing the law. The lawsuit grew from 20 to 26 states after newly empowered Republican governors asked to join. Judge Vinson declined to suspend the law pending appeals.

The Obama administration is appealing the ruling to the United States Court of Appeals and says the individual mandate is necessary in order to end insurers' discrimination against individuals with pre-existing conditions. The administration argues that without the mandate, which it dubs the "personal responsibility" provision, healthcare costs would skyrocket because people would wait until they were sick to purchase insurance.

Three federal court judges have ruled in favor of the administration. The most recent ruling on February 25 by Judge Gladys Kessler of the Federal District Court of Washington D.C. ruled in favor of the law's constitutionality thus upholding the individual mandate. Of specific note, Judge Kessler noted that when people without insurance become sick and seek care, the costs are usually shifted to other participants in the health markets, to federal and state governments, and to taxpayers. She called it "pure semantics" to argue that people who choose to forgo health insurance are not "acting," especially given the economic impact on others. "Making a choice is an affirmative action, whether one decides to do something or not do something," said Judge Kessler.

### **The Politics of Health Care**

Republicans in the U.S. House of Representatives, now in control of the lower chamber, are targeting the individual

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## Federal Judges Split 3-2 in Health Care Rulings

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mandate and other reform law provisions. House Republicans, joined by three Democrats, voted in mid-January to repeal the health care law. In early February, the Democratic led Senate rejected a Republican effort to repeal the health care law on a straight party line vote of 47-51.

President Obama who has stood by the health care law through court attacks and legislative efforts to repeal it, has stated he is willing to amend the measure to give states the ability to opt out of its most controversial requirements right from the start, including the mandate that most people buy insurance.

White House officials have also declared that the court opinions against the health care law should not deter the continuing rollout of the law. "Implementation would continue apace," the administration said. "This is not the last word by any means."

With different federal judges providing different rulings as to the constitutionality of the health care reform law, it is very likely that the law will be appealed until it is finally considered by the United States Supreme Court, where a final determination will likely be made.

Whatever may happen with the law, there would be serious concern if some of the chronic care disease-friendly provisions were eliminated and not incorporated into any replacement legislation. It will be important to remain involved and active as the issues are debated.

*patrick.collins@cslbehring.com*

### Some provisions implemented:

The elimination of lifetime insurance caps on existing insurance.

- The removal of pre-existing conditions as a barrier to insurance coverage for children—adults will have this provision in place in 2014.
- Extension of coverage for dependants who are now allowed to remain on their parent's insurance policies to the age of 26.
- The increase in the Medicaid rebate from 15.1% to 23.1% for all covered therapies (17.1% for blood clotting factors).
- The increase in the Public Health Service pricing discount for 340 B entities by the same percentages as the Medicaid rebate.

### Some provisions to be implemented:

- Implementation of a pharmaceutical fee in 2011 which as written may discourage the development of certain rare disease therapies.
- Implementation of a 2.9% excise tax on all medical devices sold.

## Did You Know?

The new Speaker of the House, John Boehner (R-OH) is the 61st person to hold this position. The longest serving Speaker of the House was Sam Rayburn (D-TX) who held the position on three separate occasions (Speaker number 48, 50 and 52) between 1940-1961.



Speaker of the House Sam Rayburn on the left and current Speaker John Boehner on the right.

