

policy impact

CSL Behring Public Policy Newsletter Winter 2011–2012

CSL Behring Awards \$40,000 LEAD Grant to A-PLUS for Development of State Insurance Exchange Project

CSL Behring has awarded one Local Empowerment for Advocacy Development (LEAD) grant to the American Plasma Users Coalition (A-PLUS) for the fall grant cycle. The \$40,000 grant will be used to assist in the creation of the A-PLUS State Exchange Project.

The project is designed to educate state advocates for all A-PLUS members on the development of state insurance exchanges and related insurance reforms stemming from the Affordable Care Act. These will specifically include the federally defined essential health benefits that will establish the minimal requirements of state insurance exchanges. The project will also help state advocates educate their constituents on how the exchanges are being implemented and how they can participate in the process. This is important in order to insure access to specialized care and treatments are being maintained in the plans offered through the state insurance exchanges.

A-PLUS is contracting with the Georgetown University Health Policy Institute in this endeavor. The National Hemophilia Foundation will serve as the fiscal intermediary for the funding and contract.

The A-PLUS State Exchange Project will have training modules on the exchanges, a personal health insurance toolkit for

Continued on page 2



A-PLUS Coalition Members

- Alpha-1 Association
- Alpha-1 Foundation
- GBS/CIDP Foundation/International
- Committee of Ten Thousand
- Hemophilia Federation of America
- Immune Deficiency Foundation
- Jeffrey Modell Foundation
- National Hemophilia Foundation
- Platelet Disorder Support Association
- Patient Services Incorporated

Inside:

- 03 Essential Health Benefits: Influential Institute of Medicine Weighs In
- 04 Key Issues Dialogue: Access to Care
- 05 Indiana Health Insurance Exchange: Work in Progress or Stalemate?
- 06 Maryland Moving Ahead With Insurance Exchange

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; Ryan Faden, Manager, State Government Affairs; Mike Vogel, Manager, State Government Affairs and Karla White, Manager, Public 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.

CSL Behring Awards \$40,000 LEAD Grant to A-PLUS for Development of State Insurance Exchange Project *Continued from page 1*

constituent use, and regular updates on the activities of the National Association of Insurance Commissioners (NAIC), including identification of opportunities for engagement with NAIC.



Larry LaMotte, Director of Government Affairs for the Immune Deficiency Foundation said, “The project will ensure each organization’s volunteers are educated and trained to advocate effectively on behalf of their respective patient populations. It will also ensure the State Health Exchanges provide

protections for all patients with rare and chronic diseases. A second benefit will be the development of trained patients to assist other patients in choosing the insurance plan that best meets their needs when the health care reform law goes into effect in January, 2014,” LaMotte said. “A third benefit of the project is that it will facilitate collaboration among users of plasma-derived therapies from the different patient communities, enabling them to work together as advocates in their respective states to affect public policies that may impact them. It’s a win-win all the way around!”



Michelle Rice, Regional Director for Chapter Services at the National Hemophilia Foundation stated, “Many of those affected by bleeding disorders have already been positively impacted by the new patient protections provided in the Affordable Care Act. The expansion of state Medicaid programs and the

creation of state health insurance exchanges in 2014 have the potential to offer consumers something

many have never experienced—choices for health care coverage. Understanding and participating in the implementation process is the only way to ensure the needs of the bleeding disorder community are addressed. A special thank you goes to CSL Behring for recognizing the importance of this initiative and their willingness to provide financial support to make it a reality.”



CSL Behring’s Senior Vice President of Public Affairs, Dennis Jackman added, “We are looking for opportunities to collaborate with patient organizations to advance advocacy initiatives. Providing a LEAD grant to A-PLUS for the state exchange project will positively impact patients represented by all

the coalition members. The state insurance exchanges are a crucially important area where education and advocacy are needed, and we are very pleased to support this effort.”

LEAD Grant Program

CSL Behring’s LEAD Grant is a community-based program that awards grants in the spring and fall. These grants help patient organizations achieve their advocacy objectives. CSL Behring awards LEAD Grants to organizations that demonstrate a need for financial assistance in order to address important advocacy initiatives.

The deadline for submitting LEAD Grant proposals for the next cycle is April 30, 2012. Interested patient advocacy organizations are encouraged to apply.

An application may be obtained at:
<http://www.cslbehring.com/patient-commitment/lead-program/lead-grant-application.htm>

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Essential Health Benefits: Influential Institute of Medicine Weighs In

Within the broader health care reform package enacted under the Affordable Care Act (ACA), one of the most critical elements is the development of the Essential Health Benefit for plans included as part of the new Health Insurance Exchanges to be implemented as part of the Act. ACA directs the Department of Health and Human Services to develop an essential health benefit consistent with the statutory language contained in ACA. As part of this effort, the Secretary of the Department asked the Institute of Medicine to develop a comprehensive document to aid the determination of what should be included within the essential benefit.

ACA includes ten broad categories that should be included in the essential health benefit in statutory language.

Essential Benefit Categories in ACA

- Ambulatory patient services
- Emergency services
- Hospitalization
- Maternity and newborn care
- Mental health and substance abuse services, including behavioral health treatment
- Prescription drugs
- Rehabilitative and habilitative services and devices
- Laboratory services
- Preventive and wellness services and chronic disease management
- Pediatric services including oral and vision care

Source: §1302(b)(1)(A-J).

The Institute of Medicine (IOM) report issued in October endorses the statutory construct that the ten categories should be utilized as the basis for establishing benefit packages for health plans within insurance exchanges. These categories are derived from the so-called typical small group/individual plans, which are the two populations that figure to be most directly impacted by the new insurance options

available as part of the exchanges. This allows for a great deal of flexibility at the individual state exchange level and even at the individual plan level. The IOM is very influential in health policy design and implementation and has an important role in essential benefits design recommendations.

There is some discussion about whether additional specific categories should be added such as home care, but that could involve additional costs, which are a central concern of the IOM report. The argument boils down to whether costs are too high for the typical plan and if so, will fewer people enroll in plans even in light of various available federal subsidies in the form of tax credits and other vehicles. Cost is a central element in the report as it was in the development of ACA in Congress and the Administration.

The IOM states that the package should be derived under a paradigm including the four domains of Economics, Ethics, Population Health, and Evidence Based Practice.

One question raised in the implementation of ACA is how do existing state mandates fit into the essential health benefits development process? Here, the IOM provides some important guidance that may have a substantial impact. Specifically, in considering options, the IOM concluded:

“Because state mandates are not typically subjected to a rigorous evidence-based review or cost analysis, cornerstones of the committee’s criteria, the committee does not believe that state-mandated benefits should receive any special treatment in the definition of the essential health benefit and should be subject to the same evaluative method. This interpretation is consistent with the language in ACA regarding state mandates; that is, Congress specifically did not require their inclusion.”

In fact, this recommendation underscores two major themes of the IOM report (Evidence-Based Practice and Economics) and what could be termed an overall change in health care financing and delivery. Specifically, under ACA and consistent with the IOM report, the coverage of various health care services and items within the essential health benefits will be subject to greater scrutiny in terms of cost and evidence of effectiveness in the future.

Continued on page 4

Essential Health Benefits: Influential Institute of Medicine Weighs In *Continued from page 3*

Moreover, the benefit is not viewed as a static list that will exist in perpetuity. Rather, the IOM recommends that feedback mechanisms are in place for ongoing evaluation and reevaluation of the inclusion of services in typical health plans. One critical entity charged with such evaluation is the National Health Benefits Council created under ACA.

Within all of these discussions on essential benefits, it is truly essential for policymakers to understand the needs of rare disease communities. Access to treatment is critical given the nature of these conditions. The LEAD grant mentioned above aims to help in assuring that access.

Elimination of Lifetime and Annual Limits

With the enactment of ACA, a critical victory was achieved for the plasma users community with the elimination of annual and life-time benefit limits in health plans. Nevertheless, there is much concern that insurers will seek ways to get around the intent of the law by finding “loopholes” that employ other de facto cost-control devices such as step therapy, visit limits, and more stringent prior authorization requirements. The IOM recommends that any evidence based limits and determinations of medical necessity should take into account the individual aspects of the patient, which would be particularly important for vulnerable rare disease patients. The bottom line is that plans comprised within the exchanges must have a transparent and consistent approach to making benefit determinations.

On a related matter, the IOM also highlights the importance of not discriminating against certain individuals:

“Insurers should not make arbitrary and discriminatory decisions based on certain characteristics of people rather than assessing the individuality of each case when making medical necessity decisions and applying clinical policies.”

In the case of many disorders treated with plasma protein therapies, some have argued that insurers have utilized practices focusing primarily on perceived cost without taking into account the unique needs of the patient.

The IOM report provides a framework that the Secretary of Health and Human Services can work with to develop the essential health benefits package. In doing so, cost and evidence-based practice will be of paramount concern. The IOM recommends that the final essential health benefit be determined by May 2012 at the latest.

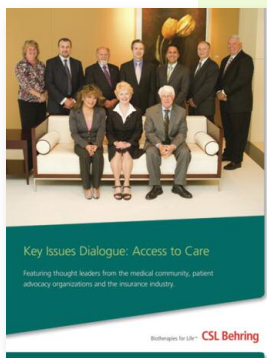
Opportunities for Public Comment

There will be substantial opportunities for public comment and input to proposed federal regulations that are expected soon. The Department of Health and Human Services recently announced a nationwide public listening tour that will take place this winter.

However, even once the benefits are finalized, much advocacy work will remain with individual state exchanges and health insurance providers in determining what specific categories and services should be included in plans that qualify for inclusion within the exchanges.

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Key Issues Dialogue: Access to Care



Recently, a group of patient advocacy, medical and insurance industry thought leaders engaged in a provocative discussion about practices that impede access to health care for Americans with rare and serious medical disorders, and possible solutions. This discussion is particularly relevant now as healthcare reform is being implemented to help assure people with rare diseases do not end up with reduced care as an unintended consequence. This recently published dialogue is available through the attached hyperlink:

http://www.cslbehring.com/docs/554/284/FINAL%2010_14_11.pdf

Indiana Health Insurance Exchange: Work in Progress or Stalemate?

Indiana Governor Mitch Daniels signed an executive order in January 2011 that directs state agencies “to conditionally establish and operate a state-based healthcare benefit exchange.”

Indiana is one of the states that is both suing the federal government over the Affordable Care Act, which requires the establishment of insurance exchanges, and preparing to comply with it.

In a statement issued after signing the executive order, Gov. Daniels expressed his concern that the health reform law was too costly and complex. But he also acknowledged that it would be in his state’s best interest to begin thinking about a framework, should legal proceedings fail. Governor Daniels stated “the nation will be best served by the repeal of this expensive and unworkable law, or by its judicial overturn,” he said. “But for now, there seems no alternative but to prepare for the possibility that Indiana will try to operate an exchange of some kind.”

Indiana has received almost \$7 million in federal grants to strengthen the health information technology systems that will be integral to its Exchange. Additional funding will support project management, legal, actuarial and financial expertise and general policy support.

Since January, little had been released to the public. Then in August, the Indiana Health Finance Committee released a report where it is estimated there are about 5.5 million Indiana residents age 0-64 and roughly 20 percent may be eligible to go onto a state based exchange or a federal insurance exchange.

The Indiana state-based exchange would open a new market for health insurance but there are many questions



Governor Mitch Daniels of Indiana



yet to be answered. As of October 11, Indiana is yet to decide if it will develop a health insurance “exchange” as part of requirements outlined by the Affordable Care Act, or allow the federal government to handle the implementation.

A recent Indiana Health Exchange Symposium sponsored by AARP brought people from all sides together to consider options. Seema Verma, healthcare reform lead for the state of Indiana, says that so far there are more questions than answers from the Federal government. “They’ve really put out almost no information about what a federal exchange would look like, so there’s nothing for us to compare to at this point.” Indiana has not committed to creating its own exchange, Verma says, but will be involved in planning and research if it’s decided that is the best option.

Benjamin Domenech, managing editor of Health Care News and a research fellow at The Heartland Institute, is urging the state to wait. “There are so many things that have to come out from Washington in terms of regulations, in terms of controls, in terms of requirements put on the state. I think that it’s important for Indiana to let that play out before they just go ahead with everything.”

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Maryland Moving Ahead With Insurance Exchange



Maryland made the decision to run its own state-based Insurance Exchange early on and has taken a very aggressive approach to its development and implementation. The Exchange was created through the Maryland Health

Benefit Act of 2011, and signed into law by Governor Martin O'Malley in April. The Exchange is governed by the Maryland Health Benefit Exchange Board, a nine-member Board of Trustees, including the Secretary of Health and Mental Hygiene, the Insurance Commissioner, the Executive Director of the Maryland Health Care Commission and six gubernatorial appointees. The Board began meeting in June and subsequently hired Rebecca Pearce to serve as the Executive Director of the Exchange.

The Maryland Health Benefit Act of 2011 charged the Board with completing six legislative studies and required a report back to the General Assembly by December 23, 2011.

Health Benefit Exchange Board Studies

- Exchange operating model
- Insurance market rules
- Navigators and consumer assistance
- Small business health options program
- Financing of the exchange
- Future status of the exchange

The studies will help guide important decisions such as whether Maryland should extend benefits beyond the essential health benefits and be an "open market" or an "active purchaser" model. Other important decisions include navigator training, functions and competencies and how the Exchange can become financially self sustaining.

To aid in the development of recommendations for the legislative studies, the Exchange Board created four Advisory Committees:

Maryland Exchange Board Advisory Committees

- Operating Model and Insurance Rules
- Small Business Health Options Program
- Navigator and Enrollment
- Finance and Stability

These advisory committees have been meeting regularly, receiving public input and working with vendors contracted by the Board to provide recommendations and options in each of their areas. The Advisory Committees and vendors are to submit their reports to the Board at the November 15, 2011 meeting. The Board will then take these recommendations under consideration for the report to the Maryland General Assembly.

Detailed information on progress to date is available on the Exchange's website:

<http://dhmh.maryland.gov/healthreform/exchange/>

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Did You Know?

The U.S. Presidential campaign of 2012 is the first time since 1900 that a sitting United States Senator is not running for President. The Democrats will nominate the current President, Barack Obama and of the multiple Republican candidates who are running, not one is a sitting U.S. Senator.

In 1900, the Republicans nominated the incumbent President William McKinley without contest while only two Democrats competed for their party nomination, William Jennings Bryan, the 1896 candidate, and George Dewey, Admiral of the Navy and hero of the Battle of Manila Bay during the Spanish-American War.



From Left to right: President William McKinley, William Jennings Bryan and Admiral George Dewey