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State sets hearings on reforming Medicaid payment process

BYLINE: kris B. Mamula

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Pennsylvania is preparing a sweeping overhaul in the way hospitals are paid for treating poor people, the biggest change in Medicaid reimbursement in decades, experts say.

The good news is government payments to Pennsylvania's 170 acute care hospitals where indigent patients are treated will increase by about \$40 million annually; the bad news is Medicaid reimbursement will still trail actual hospital costs.

The state Department of Public Welfare wants to expand ways to account for the severity of the patient's condition, leading to payments that more closely reflect the cost of providing the care, according to Michael Nardone, DPW's deputy secretary for medical assistance.

A total of \$37 million in state and federal money is available to redesign a schedule hospital administrators say is outdated and inequitable. The target date for introduction of the new payment system is August 2009, Nardone said.

"The new payment system better matches payments for medical assistance to actual costs," Nardone said. "The major advantage is that more complex cases would get weighted for acuity."

The first of three public hearings on the new reimbursement schedule will be held Sept. 10 at Carnegie Mellon University. Other hearings are scheduled for State College and Philadelphia.

"It's an opportunity for hospitals to talk about the Medicaid payment redesign, so that's an important forum," said Patricia Raffaele, vice president of the Hospital Council of Western Pennsylvania, a Warrendale-based advocacy group. "There's a disparity in the medical assistance rates in the western part of the state compared to the eastern part, and we're trying to find out the reason for that."

Critics of the reimbursement system say there are sharp statewide, and even local, disparities between comparable hospitals providing the same kinds of care for Medicaid patients. The problem is complicated by the fact that the base rates hospitals are paid, which is a component of the total reimbursement, are not readily available, so comparisons between hospitals are difficult.

Medicare's reimbursement formula assigns a numeric value to medical care provided for various problems. To better reflect the cost of treatment, Medicare last year expanded the number of so-called diagnostic related groups to reflect severity and therefore treatment costs.

DPW's reimbursement overhaul would mirror the Medicare changes, according to Paula Bussard, senior vice president of policy and regulatory affairs at the Hospital and Healthcare System of Pennsylvania, a Harrisburg-based trade group.

"All hospitals will generally be reimbursed less than the cost of care," Bussard said. "They're trying to reduce the amount of the inadequacy."

The state will increase total Medicaid reimbursement by around \$40 million a year, which is less than hospital administrators had sought, Bussard said, but an amount that will help reduce the shortfall between actual costs and government reimbursement.

The overhaul will not affect outpatient care, where the average hospital receives between 35 cents and 50 cents for every dollar of cost.

The reimbursement formula change will have a big impact at 224-bed Uniontown Hospital, where Medicaid only reimburses the hospital between 60 cents to 70 cents of every dollar of cost, according to President and CEO Paul Bacharach. The hospital admitted 10,000 people last year and treated several hundred thousand in its outpatient and medical testing centers. The statewide average for Medicaid reimbursement is around 83 cents for every dollar of cost.

"We have to make up that deficit somewhere, and generally that's through the offset in commercial insurance, which pays above cost," he said. "It's not a problem that can be fixed in one year."

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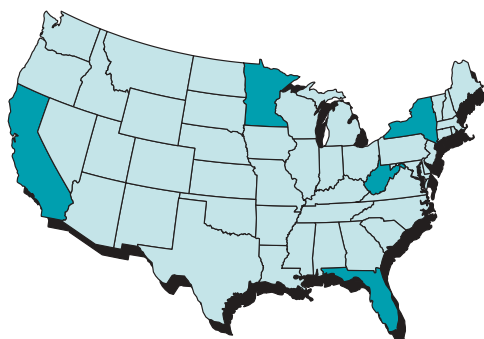
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State Actions Impact Access to Plasma Therapies

During the first few months of 2004, state legislatures and regulatory agencies have taken additional action to contain costs within their state run health care programs. While PPTA recognizes the need for states to control prescription drug costs, these actions could limit consumer access to, and choice of, plasma therapies within state Medicaid and Children's Health Insurance Programs (CHIP). PPTA continues to work with all stakeholders to ensure that the full range of plasma-derived and recombinant analog therapies are available to beneficiaries in these programs without unnecessary restriction or delay.



In West Virginia, the legislature has sent to the Governor a bill (House Bill 4084) that would create the Pharmaceutical Cost Management Council (note: plasma therapies are included in the definition of pharmaceutical contained in the legislation). One of the functions of the Council would be to consider strategies that "manage the increasing costs of prescription drugs" within the state's Medicaid and CHIP programs. During consideration of the legislation, PPTA emphasized the need for adequate reimbursement policies to ensure consumer access to the full range of therapies in West Virginia.

The Florida Agency for Health Care Administration (AHCA) continues its implementation of a hemophilia disease management program that would implement a single source provider arrangement for blood clotting factor therapies. If fully enacted, hemophilia patients in Florida's Medicaid program would be required to obtain their

blood clotting factor from a single vendor selected by the State. PPTA believes that single source provider programs unnecessarily restrict consumer choice and could compromise patient health. PPTA continues to work with both the AHCA and the Florida legislature, to ensure that any hemophilia disease management program would allow patients access to the provider of their choice and ensures access to a variety of blood clotting factor therapies.

Minnesota is also considering legislation (House Bills 1681, 2280, Senate Bill 1760) that would require the Department of Human Services to develop a hemophilia disease management program for beneficiaries in the state's Medicaid program. In developing the program, this legislation would require that the State Department of Human Services explore the feasibility of contracting with a 340B Hemophilia Treatment Center (of which there are only two in the state) to provide the disease management services. PPTA believes that this legislation, if enacted, would also serve as an unnecessary restriction on patient choice. PPTA is working with all affected stakeholders with regard to this legislation.

In New York, the State Medicaid agency has recently changed its reimbursement formula for intravenous

immune globulin (IVIG) administered in the physician office environment. As a result, several large providers of IVIG have indicated that they may not be able to continue providing this service under the new reimbursement formula. PPTA and stakeholder groups are working to emphasize that a physician's office is the preferred treatment setting for the infusion of IVIG and that any reduction in the number of physicians providing this service could compromise the quality of patient care. PPTA is also emphasizing that the costs involved in the infusion of IVIG that are not currently directly reimbursed by Medicaid were absorbed by physicians under the old reimbursement formula.

In California, Governor Schwarzenegger's proposed budget for fiscal year 2005 included significant cuts to the Genetically Handicapped Persons Program (GHPP). During meetings with the legislature, PPTA and the Hemophilia Council of California emphasized the impact that these cuts could have on consumer access to plasma therapies in California. When the Governor's budget was considered by the Senate Budget Committee, the funding for the GHPP program was fully restored. PPTA also urged the legislature and the Department of Health Services to fully implement the new reimbursement formula for blood clotting factor therapies (average selling price plus twenty percent). PPTA emphasized that the savings realized by the new reimbursement formula would be more than enough savings to fully fund the GHPP program and to ensure patient access to the full range of blood clotting factor therapies.

PPTA continues to monitor and respond to the legislative and regulatory activities in all 50 states on such issues as prior authorization/preferred drug lists/pharmacy & therapeutics committees, maximum allowable cost/reference pricing, and single source provider arrangements. For more information on PPTA's state legislative and regulatory activities, contact Scott DiBiasio at the Association Offices. ●



Reliance on Prior Authorization

In order to avoid the hard choices of denying healthcare benefits or turning away the poor, states have begun to consider a model for controlling prescription drug benefit costs that falls short of totally eliminating prescription drug coverage. Pioneered in the short-lived Maine Rx Program enacted in 2000, the prior authorization/PDL approach starts with the assumption that state Medicaid programs may partially restrict or delay access to some drugs and therapies without violating federal Medicaid law. That law requires that, if a state elects to make prescription drugs and therapies available in its Medicaid program, they must be made available to the Medicaid population to the same extent that they are available to non-Medicaid populations. They must be placed on the Medicaid formulary if safe and effective, and if the manufacturer agrees to pay rebates of 11 to 15 percent to the Medicaid program.

Under the Maine Rx approach, the state negotiates with drug manufacturers for the payment of state rebates,

“supplemental” to those already required under the federal law. Manufacturers must pay the rebates before their drugs can be considered for placement on the state Medicaid formulary or PDL. Prescribers must seek approval from the state before prescribing drugs not placed on the PDL. Only drugs placed on the PDL may be prescribed without “prior authorization.”

The theory behind the approach is that these supplemental rebates will reduce state Medicaid costs by, in effect, further discounting the prices of drugs offered through the Medicaid program. Although non-rebated drugs are still available through the program, time-pressed prescribers first have to contact the state to obtain authorization to prescribe the non-rebated drugs. The expectation is that prescribers will choose to forego the administrative burden of making prior authorization calls, and instead simply prescribe the discounted drugs ... thereby saving the state money.

Minnesota: Focused on Quality of Care

By Ryan Faden

On May 10, the Minnesota Senate introduced SF 2290 focusing on ensuring quality of care for all patients utilizing plasma protein therapies. The bill was co-sponsored by Minnesota State Senators Kathy Sheran and Sharon Erickson Ropes. Sen. Sheran has a background in education for children with special needs and Sen. Ropes has a nursing background. Both are committed to ensuring that Minnesotans receive the highest quality health care possible. To that end, they have also been very involved this year in the legislative efforts surrounding universal health care access legislation in Minnesota. While those bills did not pass this year, they are receiving considerable attention during the interim period between legislative sessions and will likely be a high priority in 2008.

SF 2290 was referred to the Senate Health, Housing and Family Security Committee. With this bill introduction, there are now two states (Pennsylvania is the other) actively considering quality of care legislation based upon the existing New Jersey law. The Minnesota legislation would, if enacted, require that:

1) Consumers have access to qualified home care providers with the requisite expertise. Under the legislation, home care providers would be required to meet the following requirements:

- Supply products and services under a prescription from the covered person's treating physician and not make any substitutions of plasma protein therapies without prior approval of the treating physician;
- Supply all needed drugs and ancillary supplies for the administration of plasma protein therapies, including, but not limited to, needles, syringes, and cold compression packs;
- Provide directly, or through a third party agency, supportive home nursing services to assist in the reconstitution and administration of plasma protein therapies when such services are prescribed by the treating physician;
- Provide record keeping and documentation and assist covered persons in obtaining third party reimbursement;
- Provide expedited notification to patients of plasma protein therapy recalls or withdrawals;

- Provide for proper removal and disposal of hazardous medical waste in compliance with applicable state and federal law and;
- Provide covered persons, upon request, information about the expected costs for medication and services that are not otherwise reimbursed by the covered person's health plan company;
- Require the Commissioner of Health to compile a list of home care providers who meet the minimum standards set out above and make the list available to health plans and to covered persons upon request.

2) Consumers have access to specialized laboratories with expertise in the complex testing associated with conditions treated with plasma protein therapies; and

3) Screening for von Willebrand's disease prior to undergoing a hysterectomy for unexplained menstrual bleeding. Estimates from the National Hemophilia Foundation indicate that as many as 30,000 women in the U.S. each year have unnecessary hysterectomies.

Earlier in May, Minnesota Governor Tim Pawlenty signed a proclamation recognizing the importance of access to plasma protein therapies.

These exciting developments in Minnesota represent an important victory in the efforts of the community to ensure that consumers receive high quality care. It is the result of members of the patient community and industry working together to achieve an important goal. PPTA is committed to continuing its work on this important issue in Minnesota through the remainder of 2007 and 2008 as the state continues to work on reforming its health care system.



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Medicaid: Biggest insurer is a budget buster

BYLINE: By Daniel C. Vock, Stateline.org

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WASHINGTON _ Medicaid went largely unnoticed when it first came into being in mid-1965, meriting only passing mention from President Lyndon B. Johnson at a bill-signing ceremony in Independence, Mo., that focused on the passage of the Medicare health plan for Americans over age 65.

But four decades later, Medicaid's numbers are eye-popping. It is now the nation's largest health insurance program, covering 59 million poor people (53 million in traditional Medicaid and 6 million in the State Children's Health Insurance Program), or one in six Americans, according to the U.S. Department of Health and Human Services. It pays for 37 percent of all births in the United States and helps foot the bills for more than 60 percent of all patients in nursing homes.

With states picking up nearly half of Medicaid's \$320 billion costs this year _ and the federal government the rest _ it's little wonder that Medicaid is constantly generating controversy in state capitols and in Washington, D.C. Cut it, and politicians face accusations of harming the country's most vulnerable citizens. But doing nothing is costly, too. Medicaid costs have been growing at 6 percent or more annually, twice the rate of inflation, and threaten to swamp state budgets.

Medicaid covers the poor and working class, but not all of them. The program is designed for low-income pregnant women, parents and children, the elderly, blind and disabled. It's limited to Americans and legal immigrants, largely those who have been in the country more than five years.

That population includes some of the sickest _ and most expensive _ patients in the health care system. States try to clamp down on those costs, but at the risk of angering doctors, dentists, hospitals, nursing homes and drug companies that provide the services.

The impact on state budgets is huge. Accounting for 22 percent of state spending, Medicaid recently surpassed elementary and secondary education as the most expensive item on state ledgers, once federal matching grants are taken into account. And because Medicaid is geared toward poor people, its expenses and enrollments climb when states can least afford them: when the economy turns sour.

In February 2006, President George W. Bush signed a budget-cutting bill that

gives states more flexibility to decide who qualifies for Medicaid, what services to offer and how much recipients should help pay for their medical care. The changes are projected to save the federal government \$6.9 billion _ and state governments nearly as much _ over five years. But the savings still amount to less than one-half of 1 percent of Medicaid spending in those years.

The changes to Medicaid marked a culmination of a yearlong lobbying effort by the National Governors Association to give state governments a freer hand in designing their Medicaid programs.

State governments can bend some of the rigid federal rules for Medicaid by getting permission from the federal Centers for Medicare and Medicaid Services (CMS). That flexibility means that Medicaid has become a kind of policy playground for governors. The result is that no state's Medicaid program is exactly like another's, leading health policy experts to say Medicaid isn't one program, but 51 (one for each state and the District of Columbia).

In hopes of bringing some light to this important discussion, Stateline.org set out to better define the Medicaid program and point you to resources that might lead to a greater understanding of what the politicians are talking about.

You'll find a great deal of basic information on a Web site maintained by the U.S. Department of Health and Human Services; click on Medicaid. The Henry J. Kaiser Family Foundation offers help at Kaiser/Medicaid and Kaiser Report. The Nelson A. Rockefeller Institute of Government has compiled still more information at Rockefeller research.

(EDITORS: END OPTIONAL TRIM)

Here are some facts at a glance in FAQ form:

Q: What is Medicaid?

A: In reality, Medicaid is not one program, but 50 different programs that states administer using broad federal guidelines and federal funds. Washington picks up about half (57 percent) of the tab, states pay the other half. In 2006, Medicaid will serve 59 million people _ more than any other single health care program in America, including Medicare.

Q: Is Medicaid the same as Medicare?

A: No. Medicare is a federal program that provides health care for some 43 million senior citizens and retirees over 65 years of age.

Until recently, states had no direct role in Medicare. But starting Jan. 1, 2006, Medicare's Part D began providing a prescription drug benefit for the first time. But unlike all other Medicare services, states will partly pay for this benefit. Plus, most states helped smooth the transition by covering the costs of seniors who couldn't get prescriptions, while the federal government and the insurance companies sorted out the details.

Medicaid and Medicare also share other costs associated with "dual eligibles" _ people who qualify for both programs.

Q: Who are "dual eligibles" and why are states so upset about them?

A: In any debate about Medicaid, state officials are certain to use the term "dual eligible," referring to 7 million elderly people who are on the rolls of both Medicare and Medicaid. These people account for more than 40 percent of total

Medicaid spending because they tend to be very poor and frail and have substantial health problems.

States not only pay for their long-term needs, but help pick up the tab for their Medicare premiums, cost-sharing and some prescription drug costs. The states argue that the federal government should shoulder more of the cost of caring for this group.

Q: Is Medicaid associated with welfare?

A: No. Almost half (48 percent) of Medicaid recipients are children. Adults, primarily low-income working parents, make up nearly a third (27 percent). Disabled Americans make up 16 percent and the elderly 9 percent, according to the Kaiser Commission on Medicaid and the Uninsured. The 1996 welfare law no longer links Medicaid to welfare. Today, most Medicaid beneficiaries are not on welfare, a striking difference from 20 years ago when three-fourths of people on Medicaid also received welfare.

Q: Who does Medicaid cover?

A: Medicaid covers 59 million Americans. The federal government tells states which groups of people they must cover and the kind of services they must provide. "Mandatory" groups include:

_ Poor pregnant women, low-income, uninsured children and some parents of low-income families

_ Low-income elderly, blind and disabled people

_ Certain low-income Medicare recipients.

_ States have broad authority to cover other "optional" groups if they want. In 2005, for example, 41 states covered pregnant women at income levels that exceed the minimum amount required by federal law.

Q: What does Medicaid pay for?

A: Medicaid pays for a variety of mandatory benefits in every state including:

_ Doctor's visits

_ Inpatient hospital services

_ Laboratory services and X-rays

_ Outpatient hospital services that are preventive, diagnostic, rehabilitative

_ Nursing home care

_ Family planning and pregnancy-related services

_ Home health care

_ Nurse-midwife services

_ Periodic screening for children under 21

Q: What are some optional benefits that many state Medicaid programs cover?

A: States can _ and often do _ go beyond required benefits. Among the most popular "optional" services are:

- _ Prescription drugs
- _ Dental services
- _ Eye glasses and hearing aids
- _ Medical equipment and supplies, such as wheelchairs
- _ Ambulance services
- _ Intermediate care for the mentally retarded
- _ Hospice care

_ Even though prescription drug coverage and ambulance transport are listed as optional, all states offer both.

Q: How much does Medicaid cost?

A: Together, state and federal governments are expected to spend nearly \$320 billion on Medicaid in 2006. Medicaid accounts for 22 percent of state budgets, when factoring in federal funds spent by states. That's up from just 8 percent in 1985. That means the growth of Medicaid spending is crowding out funding for other programs that states deliver, including education, corrections and transportation.

The federal government each year tinkers with its formula for calculating how much money it gives each state. Generally, the richer the state, the less it gets. The federal matching rate is based on states' average per-capita income and is always at least 50 percent, but could be as high as nearly 80 percent. In 2006, 12 states got the minimum 50 percent rate (California, Colorado, Connecticut, Illinois, Maryland, Massachusetts, Minnesota, New Hampshire, New Jersey, New York, Virginia and Washington) while six states got matching rates higher than 70 percent (Arkansas, Mississippi, Montana, New Mexico, Utah and West Virginia).

Because Medicaid is the biggest source of federal revenue to the states, even the slightest variation of the federal match can have a big impact on a state's budget.

Q: Why are states' Medicaid costs going up?

A: It was no surprise that Medicaid enrollment went up in the last few years when the economy took a downturn. As more people lost their jobs and income, they turned to Medicaid. But the sometimes dramatic and sustained increase has surprised some state budget and health officials.

Enrollment jumped by one-third from 2000 through 2004, but the growth has slowed since then. According to the Kaiser Commission, enrollment grew by 4 percent in the year ending June 30, 2005, and by 3.1 percent in the year after that. Higher enrollment means higher costs for states.

But even with the economy rebounding, Medicaid costs still are expected to eat up state budgets. Rising health care costs, particularly prescription drugs, play a huge role, but so do demographics. As Americans gets older, many will need more long-term and nursing home care. Medicaid already is the nation's primary long-term care program, accounting for 43 percent of total long-term care spending and paying

for nearly 60 percent of nursing home residents. Changes in the U.S. workplace also are a reason for the spike in Medicaid enrollment. More employers are opting not to provide health care insurance for their employees, forcing some working poor to turn to Medicaid. Experts say the Medicaid safety net prevented substantial growth in the number of uninsured Americans, estimated to total 36 million to 45 million people.

Q: What are states doing to curb Medicaid costs?

Q: While state revenues have been improving, state budgets still are feeling relentless pressure from Medicaid. States, which are required to balance their budgets, have tried myriad ways to cut. Between 2002 and 2005, all states reduced payments to health care providers such as doctors and nursing homes and tried various prescription drug cost controls. Thirty-eight states tightened eligibility requirements, and 34 cut benefits.

In Tennessee, for example, ballooning medical costs forced Democratic Gov. Phil Bredesen to scale back TennCare, the state's 10-year-old health care program for the poor and uninsured that went well beyond Medicaid's requirements and covered working families who couldn't afford private insurance. The state dropped 190,000 adults from TennCare's rolls to save the program. In 2006, the Tennessee Legislature approved another Bredesen proposal establishing a different type of health insurance for lower-income workers, dubbed Cover Tennessee, that worked outside the Medicaid program.

Q: What is S-CHIP?

A: Commonly called "S-CHIP," the State Children's Health Insurance Program was created in 1997 to expand health insurance coverage to children in low-income families that did not qualify for traditional Medicaid but could not afford to pay for private insurance. It's largely hailed as a successful program, but it also suffered economic woes during states' budget crises. Congress must reauthorize it in 2007.

Q: What's next for Medicaid?

A: States continue to face many challenges with Medicaid, especially in light of the Deficit Reduction Act that Bush signed in February 2006, which is projected to save the federal government \$6.9 billion over the next five years and states nearly the same amount.

The law contains many items governors pushed. It lets states make patients pay more for prescription drugs and hospital visits. It makes it harder for seniors to give away their money and then ask the government to pay their nursing home bills.

The budget-reducing measure gave governors much of the flexibility they had asked for, and already states like Florida and Kentucky are using the new authority to try new ways of managing their Medicaid costs.

But the law also imposes new burdens, most notably a provision that requires states to check each enrollee's citizenship documents to prevent illegal immigrants from receiving benefits.

Just days after signing the Deficit Reduction Act, though, Bush unveiled a new budget proposal that would further rein in federal Medicaid spending through a series of moves that would reduce federal payments to states for the program and save the federal government \$13.6 billion over the next five years.

The president wants to stop allowing some of the more inventive accounting

techniques states use to capture more federal dollars.

For example, states often tax health care providers and use that money to bring in more federal dollars. Then the states turn around and give most of the money back to the providers, so both the states and the majority of providers end up with a net gain from the transaction. The administration wants to make sure money from provider taxes is directed toward facilities with high amounts of Medicaid patients.

Bush proposed enacting the changes by administrative rules, which would not require the approval of Congress.

(EDITORS: END OPTIONAL TRIM)

Governors and state officials complain that the reductions would save money for the federal government at the expense of the states. And, they note, CMS has approved many of the contested arrangements in the past.

Meanwhile, states are experimenting with ways to expand health care coverage to the uninsured, often using Medicaid as a springboard for those efforts.

Massachusetts passed a sweeping new law in April to require that all residents buy health insurance _ and that all employers offer it. The initiative was possible, in part, because legislators were under pressure by the federal government to change the way the state paid hospitals.

Illinois' new All Kids program, which aims to offer insurance to all children who live in the state, is being paid for by savings in the Medicaid program. In fact, the vast majority of children who have signed up for All Kids already would have been eligible for insurance under the Medicaid program.

Sources: Kaiser Commission on Medicaid and the Uninsured; U.S. Centers for Medicare and Medicaid Services; National Conference of State Legislatures; National Governors Association; National Association of State Budget Officers.

(Stateline.org staff writers Kathleen Hunter, Pamela Prah and Erin Madigan contributed to this report.)

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Law ensures hemophiliacs will get drugs without wait

Patricia Rengifo

When Travis Gassman needs his medication, a waiting period can be life threatening.

Gassman, 20, has been living with hemophilia his entire life. Hemophilia is a genetic blood disease that affects mostly men and makes it difficult for them to form blood clots without medication. The disease is treated with blood transfusions and plasma therapy, commonly called clotting therapies. If treatment is delayed, the result could be fatal.

About **500** Minnesotans have hemophilia.

The Legislature passed a bill this session that ensures Minnesotans with hemophilia still have immediate access to medication that is not on the Medicaid preferred drug list. Medicaid is the federal health insurance program for low-income patients.

If people on Medicaid need a drug or therapy that is not on the insurance's preferred list, they usually must get authorization from the state before drugs can be prescribed. That takes about one day.

For hemophiliacs, who are at risk of bleeding to death without medication, a waiting period isn't always practical.

"If there is a delay, you can have long-term medical complications," said Julie Birkofer, director of health policy at the Washington-based Plasma Protein Therapeutics Association.

The list of preferred drugs for Medicaid patients is determined by a committee chosen by the state health department. If two drugs have the same effects, the less-expensive one is put on the Medicaid preferred drug list, said Sen. Linda Berglin, DFL-Minneapolis and chair of the Health, Human Services and Corrections Budget Committee. Because the list of drugs waiting to be approved is so long, it will be at least two years before clotting factor therapies will be added.

"This product is expensive no matter which you choose," Berglin said.

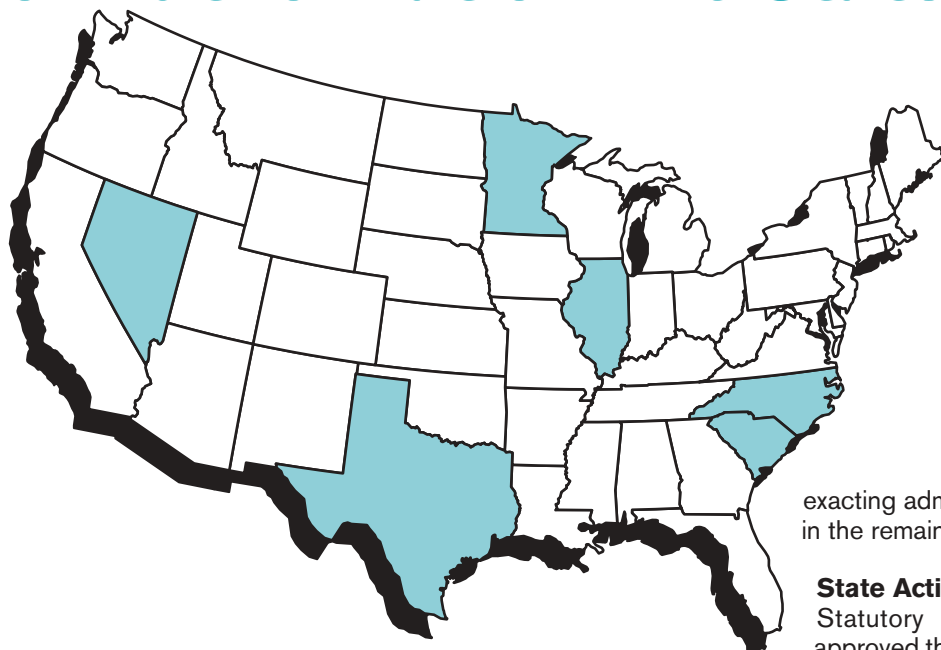
Gassman, who is on Medicaid, takes a preventative treatment twice a week. It takes about two days for his medicine to be delivered from the University of Minnesota. If there is an emergency, he has to go to the hospital.

"(The exemption) is important, especially if we need an emergency dosage," said Gassman, who lives in Hutchinson, about 50 miles south of St. Cloud.

The Washington-based Plasma Protein Therapeutics Association lobbied the Legislature to extend the exemption. It represents companies that collect plasma and use plasma to make treatments.

At least five states' legislatures also have exemptions for hemophiliacs. They are Texas, North Carolina, South Carolina, Nevada and Illinois.

Industry and Consumer Advocates Achieve Carve-Outs from Medicaid Prior Authorization in 6 States



PPTA and stakeholders have been successful in obtaining Medicaid prior authorization carve-outs for plasma therapies in six of the 22 states that have adopted such procedures. The pharmacy and therapeutics (P&T) committee for a seventh state has placed plasma therapies on its preferred drug list (PDL)

PPTA, industry, and consumer advocates are continuing to work with legislatures still in session to achieve additional legislative carve-outs, and are continuing to educate state Medicaid agencies and the newly appointed state pharmacy and therapeutic (P&T) committees about the dangers of denying timely access to plasma therapies. PPTA has mailed a letter to the Medicaid directors in all 50 states notifying them of the recent prior authorization exceptions for plasma therapies and urging them to administratively adopt similar exemptions.

Successful Coalitions

PPTA looks forward to continuing to build coalitions in states that present opportunities to assure that access and choice of plasma-derived and recombinant analog therapies is maintained. State officials from Florida and Michigan, where prior authorization procedures have been successful in cutting Medicaid costs by about 10 percent, have been traveling to other states to testify against allowing any statutory exemption to the procedures. Working together, PPTA and consumers can mitigate the impact of this testimony by emphasizing the unique nature of our life-saving therapies. PPTA and consumers will seize on the actions in these seven states to achieve additional momentum in other states enacting prior authorization statutes. Where the opportunity for achieving legislative exemptions has passed, the action in these seven states provides a model for

exacting administrative exemptions in the remaining states.

State Activity

Statutory carve-outs were approved this past session by legislators in Minnesota, North Carolina, South Carolina, Nevada, and Illinois each exempted clotting factor from prior authorization procedures, either in the legislation creating the procedures, in separate bills, or in budget language. In these five states, the carve-out took the form of a straight-forward exemption for "anti-hemophilia clotting factor therapies." In a sixth state, Texas, industry and consumers were successful in achieving a much broader, although more temporary, legislative carve-out which appears to exempt IVIG therapies as well as clotting factor. In Maine, the state Medicaid P&T Committee acted to add hemophilia clotting factor agents to the state PDL, thereby exempting those therapies from prior authorization.

In Minnesota, the existing one-year statutory exemption for clotting factor therapies, due to expire June 30, 2003, was renewed for two additional years, until June 30, 2005. The Minnesota victory was

the result of a strong collaboration between PPTA, member companies, and consumer advocates, and was won as part of the budget bill, despite strong opposition from the state Department of Human Services. In South Carolina, consumer advocates were successful in not only getting budget language (in House Bill 3749) that exempted anti-hemophilia therapies from prior authorization, but also in reversing a Department of Health and Human Services proposed administrative decision to restrict access to recombinant therapies. In North Carolina (Senate Bill 897) and Illinois (House Bill 703), the carve-out was enacted in separate legislation, while in Nevada, the carve-out was part of authorizing legislation for prior authorization procedures (Assembly Bill 384).

In Texas, legislators took a different approach, adding language to that state's prior authorization legislation (House Bill 2292) requiring the Texas Health and Human Services Commission to delay requiring prior authorization for drugs that are "used to treat patients with life-threatening and chronic illnesses that require complex medical management strategies" until the Commission has completed a study evaluating the impact of a requirement of prior authorization on Medicaid recipients. This language is believed to be broad enough to cover intravenous immunoglobulin (IVIG) therapies as well as clotting factor therapies.

Prior Authorization Pitfalls

As noted previously in the pages of *The Source*, state Medicaid prior authorization procedures threaten patient access to important life-saving pharmaceuticals and therapies – including plasma therapies. Prior authorization procedures may require patients to wait as long as 24 hours for the pre-approval of their prescriptions.

The prior authorization / PDL approach starts with the assumption that state Medicaid programs may partially restrict or delay access to some drugs and therapies without violating federal Medicaid law. Federal law does not require that

prescription drugs be made available under Medicaid—they are a so-called "optional benefit"—but every state has nevertheless adopted the benefit. However, federal law does require that, if a state elects to make prescription drugs and therapies available in its Medicaid program, they must be made available to the Medicaid population to the same extent that they are available to non-Medicaid populations. States get around this requirement by not completely denying access, but rather making access difficult. The expectation is that prescribers will choose to forego the administrative burden of making prior authorization calls, and instead simply prescribe those drugs not requiring prior authorization. In almost every state, a committee of doctors and pharmacists—the P&T committee—decides what drugs to put on the PDL. Those drugs not on the PDL are then subjected to prior authorization.

Approach Bolstered by Supreme Court

In August 2000, the first PDL/prior authorization program—the Maine Rx program—was challenged in U.S. District Court by the pharmaceutical industry. The industry maintained that Maine Rx was unconstitutional because it regulated interstate commerce, and because it conflicted with the federal Medicaid statute by denying enrollees ready access to safe and effective drugs. In October 2000, the U.S. District Court upheld the industry's arguments and enjoined the state from operating the program. After a series of appeals, the Supreme Court issued a decision in mid-May of this year that the Maine Rx program could not be challenged on the grounds suggested in the lawsuit.

This decision has bolstered the determination of states to move forward with prior authorization / PDL plans and has ensured that PPTA and consumers can anticipate a continued flurry of activity in the states on Medicaid prior authorization. However, with the victories won this year, there is now strong grounds for challenging the application of prior authorization procedures to plasma therapies. ●

Impact of Medicaid Reimbursement on Access to Therapies

By Bill Speir

Medicaid is the fastest growing segment of many state budgets.¹ Medicaid funds provide enrollees with access to vital health care services. Basic economic theory shows that access to this care depends upon adequate reimbursement. The federal Medicaid statute codifies this principle by requiring states to have reimbursement mechanisms, "sufficient to enlist enough providers so that care and services are available."² This creates a difficult balancing act for decision-makers who must control costs while ensuring enrollees access to health care.

A common cost control strategy employed by most states in recent years is to reduce reimbursement levels for pharmacy services. This creates access problems for Medicaid enrollees when the reimbursement becomes so low that providers are unable to provide the therapies. This situation often arises when acquisition costs are greater than reimbursement, commonly referred to as being "under water."

The basic formula for reimbursement is ingredient cost of the drug plus a dispensing fee, which is designed to approximate the costs associated with preparing the drug and other miscellaneous costs associated with the practice of pharmacy. Some states include a copayment in their reimbursement structures. States currently set ingredient cost reimbursement based on the four pricing concepts below:

- **Average Wholesale Price (AWP)** is the average price that wholesalers charge entities in the retail class of trade.
- **Wholesale Acquisition Cost (WAC)** is the average net cost the wholesaler pays the manufacturer.
- **Federal Upper Limit (FUL)** is the maximum amount to be paid for a drug as established by the federal government. State Maximum Allowable Charge (SMAC) is the maximum amount a state will pay for selected multi-source and generic drugs; these can be lower than FUL prices.

To reduce pharmacy reimbursement costs states may: 1) reduce ingredient cost reimbursement; 2) reduce the dispensing fee; and/or 3) increase the enrollee copayments.

The enactment of the Deficit Reduction Act of 2005 (DRA) provides options for states in reducing pharmacy reimbursement by providing more information about the costs of prescription drugs and biologicals, and allowing states to charge higher copayments. The DRA requires the federal government to provide states with Average Manufacturer Prices (AMP) on a monthly basis. AMP prices are believed to be lower than the methods described above. This may result in states changing their ingredient cost reimbursement to AMP-based reimbursement to contain pharmaceutical costs in their Medicaid programs.

Prior to the passage of the DRA, an enrollee's copayment could not be more than a "nominal" fee and a pharmacist could not deny the recipient the product if they did not pay the copayment, these amounts typically ranged from \$1 to \$3. Under the DRA, states may require aggregate copayments up to 5 percent of an enrollee's income and allow pharmacists the right to deny prescriptions when the enrollee does not pay the copayment. It should be noted that many observers have speculated that the increased administrative burdens associated with copayment enforcement and tracking would exceed any additional savings resulting from the copayments.

Reduced reimbursement levels may result in providers deciding to no longer serve patients within the Medicaid program. A parallel can be drawn to the impact lower reimbursements for IVIG have had on the Medicare program.³ The federal government reduced the reimbursement for IVIG to Medicare physicians beginning in January, 2005. The reimbursement did not equal the physician's cost for providing the IVIG to patients. As a result, many physicians stopped providing IVIG and their former patients received their IVIG treatment in hospital outpatient facilities. Physicians referring Medicare patients to hospitals have found that hospitals are sometimes unable to procure the same products, thus in some instances, requiring more time for clinical monitoring. Reductions in



a state's Medicaid prescription drug budget could have the same potentially negative impact on patient access if reimbursement for plasma protein therapies is reduced to save costs.

PPTA is concerned that reductions in state Medicaid pharmacy budgets could ultimately lead to unintended increases in the state's total Medicaid costs and poor health outcomes for its Medicaid enrollees that need plasma protein therapies. Reimbursement should be sufficient to ensure access to care for Medicaid enrollees who require life-saving plasma protein therapies to lead healthy productive lives, because access to care equals quality care.⁴

For further information, please contact Bill Speir, Manager of PPTA State Affairs, at bspeir@pptaglobal.org.

¹ THE FISCAL SURVEY OF STATES: JUNE 2007, the National Governors Association and the National Association of State Budget Officers.

² 42 U.S.C.A. §1396a(a)(30)(A)

³ Assessing the Cost of IVIG Infusion Services in Physician Offices & Hospital Pharmacy Departments, The Lewin Group (March 23, 2006).

⁴ See Aiming Higher: Results from a State Scorecard on Health System Performance, The Commonwealth Fund (June 13, 2006).

HEALTH CARE DEBATE HEATS UP DURING U.S. ELECTION YEAR

BY RYAN FADEN

THE KAISER FAMILY FOUNDATION ESTIMATES that there are 46.5 million uninsured Americans. Of this total, 9.4 million are children. As a result of the growing ranks of the uninsured, universal health care is one of the top domestic policy issues for the 2008 Presidential elections. In fact, a recent survey found that 68 percent of U.S. adults support a requirement that all residents obtain health insurance, with government subsidies for those who cannot afford coverage. Of course, the devil lies in the details. States have often played the role of “laboratory” to develop solutions to major public policy issues. In fact, in 2007 close to two-thirds of the states considered some plan to address the uninsured. Among those, at least 20 were comprehensive approaches to ensuring universal access to health care coverage. Three states, Massachusetts, Maine and Vermont, currently have programs in place, and many other states have looked to the Massachusetts plan as a model.

Universal Health Care in California: Framing the Issue

As the most populous U.S. state, California faces significant challenges in ensuring universal access to health care coverage. This is compounded by the fact that California also has the seventh highest uninsured rate in the country. Recent estimates by the California government show that 6.6 million Californians lack health insurance—approximately 15 percent of the population. By comparison, this is more than the entire population of Massachusetts (6.3 million). Of those lacking insurance in California, 1.3 million are children. The California proposal passed the Assembly late in 2007, but stalled in the Senate and faces major obstacles in the coming months. Specifically, here are some of the key concerns:

- 1) Should residents be required to buy insurance, and if so what can be done about people who cannot afford the coverage;
- 2) Are tax breaks preferable to direct subsidies for lower income workers;
- 3) How much should companies be fined that refuse to offer insurance to their employees;
- 4) How much to tax doctors and hospitals to raise money for subsidies;
- 5) Whether to require insurance companies to issue coverage to individuals, regardless of their age or pre-existing medical conditions; and finally
- 6) Funding.



Proposal Highlights

When assessing universal health care proposals, plans essentially fall into two categories. One is a single payor system in which the state functions as the sole payor for all health care services. This model would resemble some plans in other industrialized countries and raises important concerns about price controls and other mechanisms that could have negative effects on the biotechnology and pharmaceutical industries and patient access. The other approach involves so-called coverage expansions of both the existing public and private systems. The Massachusetts plan and the California proposal Assembly Bill X1 1 (this connotes the first bill of the first extraordinary session of the 2007-08 California Legislature) include an individual mandate requiring every citizen in the state to have insurance. Among the key characteristics of the California expansions are:

- 1) Coverage for all children at or below 300 percent of the federal poverty level (FPL), regardless of immigration status;
- 2) Extension of Medi-Cal coverage to 19 and 20 year olds up to 250 percent of FPL;
- 3) Coverage for low-income parents of children on Medi-Cal and childless adults between 100 and 250 percent of FPL;
- 4) Subsidized coverage for parents otherwise not eligible for Medi-Cal and childless adults between 100 and 250 percent of FPL; and
- 5) A program for childless adults who are citizens, nationals, or qualified immigrants with incomes up to 100 percent of FPL.

One key point in terms of funding the plan is securing federal financial participation (FFP) for the subsidized coverage. As a reference point, the federal government currently pays on average 60 percent of all dollars spent on Medicaid and 72 percent of those for the State Children's Health Insurance Program (SCHIP).

Reforming Health Insurance

The California proposal also includes a number of health insurance reforms. Most important among these reforms is the requirement for guaranteed issue and

renewal, which means that all carriers who sell individual coverage must offer, accept and renew such coverage to all individuals regardless of age, health status, or claims experience. This requirement could be especially important for users of plasma protein therapies who have experienced difficulties with insurance—particularly when changing jobs or after exceeding life-time maximums.

The proposal also would establish a new California Health Care Cost Quality and Transparency Committee for the purpose of statewide data collection, measurement and analysis of health care costs, quality and outcomes. This entity might discuss quality of care and standards legislation aimed at the plasma protein therapies community. It should be noted that AB 8, which was the other leading health care proposal vetoed by the Governor, includes a requirement that the California Health Services Agency conduct a review of best practices related to the care and treatment of patients with high-cost, chronic conditions. This could be highly important for users of plasma protein therapies and an issue for the community to raise in future discussions with the California legislature.

Outlook

One of the major obstacles to enacting the plan is financing. Ultimately, this will be the most important test for the proposal as the financing mechanism will be voted on by Californians in November. Because of its large and diverse population, any movement on universal health care in California could presage further development both in other states and nationally as well. PPTA is engaged and focused on this very important issue and will continue to update members through *The Source* and other communication mediums. ●

Note: California ABX1 1 failed in the state's Senate Health Committee in late January.

8 of 1000 DOCUMENTS

Fort Wayne Journal Gazette

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Home Edition

Bitter pills to swallow Medicaid, pharmacies debate effect of reimbursement cuts

BYLINE: Michael Schroeder The Journal Gazette

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Veteran pharmacist W. Howard Bell is in his element preparing and dispensing medications.

But the owner of the Pharmacy of Canterbury is part of a dying breed - independent pharmacy operators. Independent pharmacies have struggled to adapt to Medicare Part D, many enduring losses from lower reimbursement and lagging payments.

And small pharmacies battle stiff competition from large-chain drugstores and mail-order drug sales.

Now they're bracing for Medicaid cuts that an industry-sponsored study says could close one-fifth of retail pharmacies in the U.S.

Bell says his pharmacy currently breaks even on Medicaid business. About 15 percent of those who get drugs at Bell's St. Joe Road pharmacy use the governmental program which provides coverage for low-income families and individuals who meet eligibility requirements.

Bell worries about the effect of planned Medicaid reimbursement cuts, part of a federal effort to reduce the deficit. More than 11,000 pharmacies across the country could close because of reduced reimbursements, according to a study released last month by the National Association of Chain Drug Stores and the Food Marketing Institute.

Medicaid officials dispute the stark projections. They consider the study flawed and its data dated.

State Medicaid officials say Indiana's method for figuring reimbursement rates differs from the federal method, insulating it from drastic changes that could close pharmacies. But Bell has no trouble accepting the study's central finding.

"That's realistic" - he said of the 11,105 pharmacies the study projects could close. And Bell said his own pharmacy is at risk.

Bell says reducing Medicaid reimbursement rates would mean the pharmacy would be filling prescriptions for Medicaid beneficiaries at a loss. The Pharmacy of Canterbury, which gets at least 95 percent of its revenues from prescription drugs, has little to offset reimbursement decreases.

"We don't have motor oil or tires to sell," Bell said.

For now, a preliminary injunction motion filed in November by the National Community Pharmacists Association and the National Association of Chain Drug Stores has prevented Medicaid reimbursement reductions from taking effect, pending further review.

Stephen W. Schondelmeyer, a Minnesota-based pharmacy professor who previously provided expert analysis for the Centers for Medicare and Medicaid Services, testified about how the cuts could affect people's access to pharmacies. His projection that about 20 percent of the nation's retail pharmacies could close in the next few years forms the basis for the industry study. He said pharmacies in rural or inner city urban areas are most vulnerable to closing.

Industry insiders believe large stand-alone pharmacy chains and retailers with pharmacies that sell groceries and other non-drug-related items would be most equipped to absorb the reduction. Still, with slim margins on groceries, even those stores could feel the effects.

"In many rural and urban communities, supermarkets provide the only pharmacies able to serve Medicaid patients," said Tim Hammonds, president and chief executive officer for the Food Marketing Institute, which represents food retailers and wholesalers. "By reducing Medicaid reimbursements as this law requires," Hammonds said in a statement, "many pharmacies would be forced to close, and low-income Americans would have to travel many miles to obtain vital medicines."

A prominent Medicaid official disputes the doomsday projections.

"It doesn't match any analysis that we've done," said Herb Kuhn, deputy administrator of CMS and acting director of the Center for Medicaid and State Operations. "You really question the validity of the data that they were using."

In his estimate, Schondelmeyer assumed that all pharmacies currently losing money - or 13 percent based on 2001 data, the most recent publicly available - and about 15 percent of pharmacies earning less than 5 percent profits could close as a result of Medicaid reimbursement changes. But Kuhn argued that many of those losing money in 2001 may have already closed for various reasons.

He added that Medicaid has historically been generous in reimbursing pharmacies for drugs, overpaying for prescriptions on many occasions. Changes in reimbursement are designed to make payments more accurate, Kuhn said.

If reimbursement changes take effect, the government estimates it will save \$8 billion over five years (spending an estimated \$120 billion in Medicaid drug reimbursement during that period). Medicaid reimbursement cuts - part of the Deficit Reduction Act of 2005 - would decrease reimbursement rates by about 6 percent once fully phased in. The savings amount to less than 1 percent of total prescription drug sales, said Kuhn, who didn't think it would have the sizable influence that pharmacy industry groups claim.

Medicaid business makes up only about 7 percent of pharmacy business overall, said Chrissy Kopple, a spokeswoman for the National Association of Chain Drug Stores. But she said rural and urban areas' pharmacies see a disproportionate number of Medicaid customers. (She added that the percentage of pharmacies losing money or slightly profitable doesn't change much from year to year.)

Kopple also said the amount Medicaid reimburses pharmacies for drug acquisition costs is only half the equation. Reimbursement covers the prescription itself and a

"service" or a dispensing fee. According to industry estimates, Medicaid's average dispensing fee is \$4.50, compared with \$10.50 - the average cost of dispensing. So the industry has to make up for lower dispensing fees with higher product payments, Kopple said.

A CMS official couldn't say whether there was a disparity between actual dispensing costs and the dispensing fee, based on government research. He stressed that the fee was lumped in with payments for estimated drug acquisition costs.

How reimbursement rates are figured can vary by state. Overall, Indiana was below average - a good thing - in the percentage of retail pharmacies that the industry-sponsored study projected would close because of Medicaid reimbursement cuts.

The state-by-state analysis done by professional services firm PriceWaterhouseCoopers found that 13.5 percent of Indiana's retail pharmacies - or 150 - could close as a result of Medicaid cuts; that compares with New York - which had the highest projected rate of closure at 40.2 percent.

Indiana Medicaid officials believe pharmacies in the state will be insulated from federal changes to reimbursement.

"For providers around the state and especially for Medicaid providers this is a non-issue," said Dr. Jeff Wells, director of Indiana Medicaid.

Larger pharmacy chains and retailers with in-store pharmacies around the country will face different challenges, depending upon how state Medicaid programs are run. Wal-Mart, for one, isn't expected to close any stores because of reduced reimbursement.

Theoretically, the retail giant could benefit from increased traffic if smaller stores closed. But its profit margins for Medicaid business are already slim, said Scott Lahren, district pharmacy manager. If reimbursement falls below profitable levels, he said, increased business would only mean absorbing increased losses.

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MEDICAID CUTS

\$93.1 billion: expected Medicaid outpatient drug expenditures from 2008 to 2011

\$7.25 billion: projected reduction in Medicaid payments to retail pharmacies during that period based on planned cuts

7.8 percent: decrease in total Medicaid prescription expenditures based on cuts

55,561: retail pharmacies in the U.S.

11,105: number that could close because of Medicaid cuts, according an industry-sponsored study. Medicaid officials dispute the projection.

1,109: retail pharmacies in Indiana

150: number that could close because of Medicaid cuts, according to the same study. State Medicaid officials dispute the projection.

Sources: Centers of Medicare and Medicaid Services; "Impact of the Deficit Reduction Act of 2005 on Pharmacies by State," a study released in May by the National Association of Chain Drug Stores and the Food Marketing Institute.

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CORRECTION:

GRAPHIC: Caption: Photos by Laura J. Gardner - The Journal Gazette: Technician-in-training Regina Moore sells vitamins to Robin Anglin at the Pharmacy of Canterbury. Photo 2: Pharmacist W. Howard Bell looks through prescriptions at his business, the Pharmacy of Canterbury. He worries about the effect of planned Medicaid reimbursement cuts, part of a federal effort to reduce the deficit. Photo 3: Technician-in-training Karen McCormic, senior certified technician Carolyn Wiseman, and technician-in-training Regina Moore fill prescriptions.

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Limiting Patient Choice:

Bad Medicine for All Concerned

Choice of Plasma Therapies At Risk for Medicaid Enrollees

A number of state Medicaid programs, faced with ever-escalating state budget deficits, are acting to reduce the choice of plasma-derived and recombinant analog therapies ("plasma therapies") that are made available through state Medicaid programs. They are taking these actions even though the federal Medicaid law requires that the amount, duration, and scope of care and services available under a state Medicaid plan must be at least equal to the amount, duration, and scope of care and services available to the general population in the state.

PPTA, its member companies, and consumer/patient advocates continue to work in the various states to modify or defeat such proposals, so that patients can continue to have access to the full range of choices in plasma therapies.

As discussed in the last issue of *Source*, many states are considering legislation that would allow or require their state Medicaid agencies to adopt prior authorization /preferred drug list programs. The prior authorization/preferred drug list (PDL) approach starts with the assumption that a state Medicaid



program may partially restrict or delay access to some drugs and therapies without violating federal Medicaid law, as long as the process does not totally deny access to all therapies within a drug category. The state Medicaid program creates a PDL comprised generally of less costly drugs or drugs for which manufacturers have agreed to pay additional rebates or offer greater discounts. Prescribers must seek approval from the state before prescribing drugs not placed on the PDL. Only drugs placed on the PDL may be prescribed without "prior authorization".

In South Carolina, Governor Mark Sanford announced, on February 13, that the state would be implementing a prior authorization and PDL program under Medicaid. Drugs on the preferred list would be those "judged to be the most effective in their treatment class". Drugs not on the list would require pre-approval by the state before they could be prescribed. Manufacturers of the drugs not on the PDL could pay the state to get on the list by rebating the difference between the cost of their product and the price of the product on the preferred drug list. Gov. Sanford urged state legislators to be "on guard" against efforts by manufacturers to carve out special PDL exemptions, saying that exemptions could "severely undermine the whole approach of negotiating discounts in return for inclusion on the list".

At the same time that the Governor made his announcement about expanding prior authorization under Medicaid, state agency officials running the South Carolina Hemophilia program suggested that reimbursement for recombinant clotting factor therapies through the program – which covers Medicaid and non-Medicaid patients – might be barred, and that moneys for certain ongoing intensified clotting factor treatments might be cut by a third.

Advocates for the South Carolina hemophilia community immediately went to work. At press time, it appeared that they had been successful in getting language added to the South Carolina

budget which would exempt clotting factor therapies from prior authorization. It also appeared that the state budget would contain language emphasizing the need to have continued access to recombinant therapies.

In Washington State, the state Medicaid agency began, last fall, treating all clotting factor therapies as interchangeable multi-source drugs. Under this approach, cost became the primary consideration in making therapies available under the Medicaid program, without regard to clinical effectiveness. PPTA responded to this change in policy on April 11, 2003, writing the Washington State Medicaid director to question the legality, under existing state regulations, of treating a whole category of branded, single source therapies— which

The effectiveness of specific therapies may vary with different populations, and with specific individuals, because a patient's clinical response may vary with his or her comfort level in using the therapy dispensed.

are neither pharmaceutically or therapeutically equivalent—as multi-source therapies.

In Florida, Agency for Health Care Administration (AHCA) officials announced in February that they are studying an approach similar to that being used in Washington State, but for intravenous immunoglobulin (IVIG) therapies. As in Washington State, PPTA suggested to the AHCA Medicaid pharmacy director in early April that, because IVIG therapies are approved for different clinical indications and are not pharmaceutically equivalent, they should not be treated interchange-

ably as multi-source drugs. PPTA pointed out to the Florida Medicaid director that different therapies may require different dosages and different regimens, and may be appropriate only for specific populations. The effectiveness of specific therapies may vary with different populations, and with specific individuals, because a patient's clinical response may vary with his or her comfort level in using the therapy dispensed. PPTA noted that a patient who is uncomfortable with his or her therapy is more likely to fail in complying with the medication regimen prescribed by his or her caregiver. PPTA stressed that the prescriber best knows the appropriate therapy for his or her patient.

Other states are considering two additional approaches to limiting costs that could also limit patient choice. Under one approach, the state would contract with a single home health provider, who would provide therapies through a disease management program through which all enrollees would receive their therapies. Enrollees would be limited to the therapies made available by the contracted home health provider, who would be free (and in most states encouraged) to contract with the manufacturer who made the best deal with the provider. The clinical effectiveness of the therapy would be a secondary consideration.

A variation of the disease management approach would be to limit choice to one manufacturer's products through direct purchase by the state. Again, therapies would be provided through a disease management program, but one run directly by the state. In each case, patient access would be limited to choices pre-determined by the state, and the state would be required to get special permission from the federal Centers for Medicare and Medicaid Services to so limit choice.

PPTA expects that, as states continue to scramble for dollars to keep Medicaid pharmacy programs afloat, they will continue to attempt to control costs by controlling access and choice. ●

The Alabama Experience

States continue to attempt to address their budget deficits by focusing on health care expenditures. Rising prescription drug costs continue to account for a large portion of those increases. Although, PPTA recognizes the fiscal dilemma faced by the majority of states, the Association in unison with its stakeholders has long maintained that doing so should not be at the expense of patient access to lifesaving plasma protein therapies (collectively, “plasma-derived and recombinant analogs”). PPTA and its stakeholders are ever vigilant that changes in reimbursement in state Medicaid programs do not diminish access to plasma protein therapies and also maintain access to providers that deliver comprehensive quality care.

A recent example of a State in economic trouble turning to health care expenditures for relief is Alabama. Although Alabama’s latest attempts to control costs could have impacted the bleeding disorders community, it is important that the community responded because such precedents that could negatively impact patient access must be vigorously opposed and, in the best interest of preserving patient access, defeated. It is also important to constantly focus on differentiating plasma protein therapies from traditional pharmaceuticals in all aspects of the continuum

and Human Services (HHS) to provide discounted prices on covered outpatient drugs to a list of “covered entities.” In fact, the 340B program was created to encourage pharmaceutical manufacturers to offer discounts to these covered entities that are outside the Medicaid program and thus not able to obtain Medicaid rebates under a Medicaid Rebate Agreement.

Under this 340B Drug Pricing Program, a manufacturer enters a Pharmaceutical Pricing Agreement with HRSA in which it agrees to charge covered entities no more than the “PHS ceiling price” for its products.

WORKING TOGETHER FOR PATIENT ACCESS

On November 28, 2006 the Pharmacy Director of Alabama Medicaid sent a letter to hemophilia distribution providers announcing a change in the reimbursement methodology for hemophilia factor concentrates. This methodology would have been based upon Public Health Service (PHS) pricing. PPTA and stakeholders contended to the agency that implementing a reimbursement mechanism preventing providers who do not have access to PHS pricing from the 340B drug discount program from servicing Medicaid beneficiaries would not be in the best interest of Alabama Medicaid beneficiaries and not consistent with the purpose and intent of the 340B program.

"It is also important to constantly focus on differentiating plasma protein therapies from traditional pharmaceuticals in all aspects of the continuum of care."

of care. Such as orphan populations served, fragile, rare often chronic diseases; lack of interchangeability among therapies, no generic alternatives; importance of maintaining the sanctity of the physician/patient relationship; the lengthy and cost intensive manufacturing process and robust regulatory environments to name a few.

BACKGROUND

Section 602 of the Veterans Health Care Act of 1992 (“VHCA”) enacted the 340B Drug Pricing Program. That statute requires drug manufacturers, as a condition for federal funds to be available to purchase their products under both Medicaid and Medicare Part B, to enter into an agreement with the Secretary of the Department of Health

Beneficiaries receiving services from Alabama Medicaid and other government health care programs should not be denied timely access to the treatments they need to keep them alive and functioning. Utilizing PHS pricing could cause numerous providers of hemophilia therapies to decide to discontinue providing hemophilia therapies to their patients. Such approaches may result in single source provider situations. PPTA working in conjunction with stakeholders has long maintained the policy that single source provider arrangements adversely affect access to the full range of therapies. Specifically, the single provider may choose to furnish a limited selection of therapies. According to the Medical and Scientific Advisory Council of the National Hemophilia Foundation, access to the full



range of licensed hemophilia therapies is essential for optimal treatment (MASAC Recommendation #168; Regarding Access to Care for Patients with Bleeding Disorders). Delayed access to the appropriate clotting factor for the patients' unique condition can cause painful and crippling injury to a hemophilia patient's joints and organs. Such complications also often lead to increased costs for medical assistance programs for hospital, skilled nursing and other specialty services.

Patients and their physicians make informed decisions regarding the particular therapy they will utilize. Hemophilia therapies are not interchangeable and open access to all products should remain unimpeded. Each therapy has been approved by the federal Food and Drug Administration (FDA) for specific clinical indications. These are branded therapies, with no generic substitutes. Different therapies may require different dosages and regimens, and may be appropriate only for specific populations. Further, the effectiveness of particular therapies may vary with different populations or with specific individuals. Failure to maintain open access to this full range of licensed therapies could result in the adverse health outcomes discussed above.

OUTCOME – ACCESS RESTORED

On January 5, 2007, the Medicaid Agency stated in a letter to interested parties that "in response to the comments we have received regarding this proposed rule, the Agency will not move forward at this time with the proposed hemophilia reimbursement change." This was a victory for the whole community. Additionally, as other states choose to pursue similar reimbursement changes this year, the actions undertaken in Alabama by industry, patients, and providers represent a blueprint for the community.

1) *42 U.S.C. § 1396r-8(a)*

FROM COAST TO COAST U.S. PATIENT ACCESS ADVOCACY INITIATIVES

BY RYAN FADEN AND BILL SPEIR

Looming State Budget Deficits Portend Cuts for Health Care

Florida advocates meet with legislators

Floridians committed to raising awareness for persons with bleeding disorders and primary immunodeficiencies traveled to the state capital in March to advocate on behalf of individuals with rare, chronic, genetic diseases. PPTA staff was delighted to join this energized group and meet with legislators including Rep. Aaron Bean, Chairman of the House Healthcare Council.



SHUTTERSTOCK

These decision-makers were informed of the need to ensure patient access to the appropriate medical therapy and medical provider. As a bellwether state, Florida is an indicator of what may occur in other states facing budget problems—many states tend to follow the lead of Florida and other states with larger budgets or specialized programs when it comes to managing budget issues.

When the legislature began crafting the 2009 budget, it faced a deficit of \$3.4 billion. The Health and Human Services Appropriations Committee chairmen in both the House and Senate were directed by their respective leadership to cut between \$750 million to \$1 billion from their budgets. In March, the Florida Senate proposed a budget that would eliminate Medically Needy and Medicaid Aged and Disabled (MEDS/AD) as eligibility categories in order to save \$300 million.

An individual qualifies for Medicaid as Medically Needy when the cost of their care effectively reduces their income to Medicaid levels. MEDS/AD is an optional Medicaid eligibility category that allows elderly and disabled individuals to receive Medicaid benefits if their income is at or below 88 percent of the federal poverty level. Currently, that level is \$10,400 for individuals and \$14,000 for a two-person household (see chart on page 19). There

are more than 20,000 individuals in these eligibility categories, including 33 with hemophilia.

The patient community, including both Florida chapters of the National Hemophilia Foundation, bombarded the legislature with communications requesting that they refrain from cutting these two eligibility categories. On April 23, 2008, budget conference negotiators from the House and Senate agreed to fund Medicaid services for these individuals with nonrecurring dollars from a state reserve fund, virtually guaranteeing that coverage for persons with bleeding disorders will be on the chopping block again next year.

California Standards of Service legislation overcomes key hurdle

The Hemophilia Council of California has endorsed legislation on Standards of Service for individuals with hemophilia in the state. The Council's endorsement was pivotal in getting the legislation introduced. In consultation with the Council, PPTA offered public support for the legislation through letters to bill author Sen. Darrel Steinberg and to Sen. Sheila Kuehl, the Chair of the Senate Health Committee, as well as by supporting the bill during the hearing. The legislation passed unanimously out of the Senate Health Committee (11-0). This vote marks another crucial step for the bleeding disorders community as it strives to raise awareness and to promote the importance of high-quality care for consumers. The legislation now has been placed in the "suspense file" (hold) of the Senate Appropriations Committee for consideration. That committee produced a report that indicated a small, but not insignificant, financial impact of the bill. Given the current environment in the California budget—an estimated deficit of \$17 billion—any additional outlay could be considered a budget buster. The Hemophilia Council of California continues to lead efforts towards standards of care legislation, and PPTA is pleased to offer its assistance in helping to continue the momentum of this legislation in California.

State budgets in crisis on opposite coasts

These two examples show that advocacy and public policy decision-making are inextricably linked with state budget conditions. In early 2007, the National Conference of State Legislatures made public statements that budgets looked favorable in the short term, but that problems could occur in later years. Less than a year later, the Center for Budget Policy and Priorities now indicates that 27 states will face budget deficits in 2008. This abrupt reversal was caused primarily by the breadth of the sub-prime mortgage crisis and all of the associated impacts on state treasuries, particularly in the form of reduced property tax revenues.

Of these 27 states, specific estimates are available for 22 states and the District of Columbia. The combined deficits of these 22 states, plus the District of Columbia, are expected to total at least \$39 billion for fiscal year 2009, which begins July 2008 for most states. This total represents approximately 9 percent of these states' general fund budgets. Moreover, the number of states facing budget shortfalls may grow during the year as conditions on the ground continue to evolve.

In states facing budget deficits, the consequences could be severe—for residents as well as the overall economy. Unlike the federal government, states cannot run deficits when the economy falters because of their own individual constitutional requirements. As such, they must cut expenditures, raise taxes, or draw down reserve funds in order to achieve balanced budgets. Even if the U.S. does not fall into an actual recession, actions will have to be taken to close the budget gaps that states are now identifying. The experience of the last recession in 2001 will be instructive in predicting what kinds of actions states may take. These actions



The Hemophilia Council of California continues to lead efforts towards standards of care legislation, and PPTA is pleased to offer its assistance in helping to continue the momentum of this legislation in California.

can basically take three forms:

1. Cuts in services like health and education;
2. Tax increases; or
3. Cuts in local services or increases in local taxes.

As PPTA reflects on state advocacy so far in 2008 and looks ahead to its efforts in 2009, these budget realities must be kept in mind. When states are in fiscal crisis, it becomes that much more difficult to maintain access to health care services, let alone seek expansions or exceptions from state cost-containment efforts. From the Pacific to the Atlantic coasts, and in between, budget deficits will continue to play an increasing role in patient access. Accordingly, these developments underscore the importance of advocating effectively to differentiate plasma protein therapies from traditional chemical pharmaceuticals and other biologics. Educating policymakers about the vulnerable populations in the consumer community and why they are an important constituency is a shared responsibility among all stakeholders. Complacency is not an option. ●

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2008 HHS Poverty Guidelines

Persons in Family or Household	48 Contiguous States and D.C.	Alaska	Hawaii
1	\$10,400	\$13,000	\$11,960
2	14,000	17,500	16,100
3	17,600	22,000	20,240
4	21,200	26,500	24,380
5	24,800	31,000	28,520
6	28,400	35,500	32,660
7	32,000	40,000	36,800
8	35,600	44,500	40,940
For each additional person, add	3,600	4,500	4,140

Source: Federal Register, Vol. 73, No. 15, January 23, 2008

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New York Times

22 States Limiting Doctors' Latitude in Medicaid Drugs

By RICHARD PEREZ-PEFJA

In one of the most successful efforts to rein in the fast-rising cost of Medicaid, the government health plan for the poor, states are limiting which drugs doctors can prescribe for Medicaid patients.

Two years ago, only three states had authorized the use of lists of preferred drugs for such patients; since then, 19 other states have done so, though not all their programs are up and running, according to the National Conference of State Legislatures.

New York State, which spends far more on Medicaid than any other state, is moving toward joining that group, with the Senate and Assembly deep in negotiations over a bill that officials in both houses say could win approval in the week remaining in this year's legislative session. A similar program is under consideration in New Jersey.

Preferred drug lists steer doctors away from some of the most expensive drugs and toward different, less expensive ones that the state deems equally effective, a practice that many private insurance companies and employee health plans have adopted and that is being considered by Congress as part of a government-subsidized drug benefit for 40 million Medicare recipients. Such limits have persuaded pharmaceutical companies to lower the cost to states of some medicines. Doctors who want to deviate from the list must get prior approval, a process whose difficulty varies widely from state to state.

Medicaid officials in Florida say their program is saving more than \$200 million a year, Michigan officials say theirs cut costs by \$45 million a year, and some legislators in New York predict annual savings for their state as high as \$400 million. Such claims are difficult to judge, because states negotiate below-retail prices and rebates

with drug makers but keep those figures secret at the manufacturers' insistence.

Health care experts say the potential savings nationally from the use of preferred drug lists, or formularies, could reach into the billions of dollars. It is one of several steps states have taken in recent years to try to control Medicaid costs, including moving recipients into managed care plans.

"Containing prescription drug costs is at the top of nearly every state's agenda, and this could be an effective strategy for doing that," said Diane Rowland, executive director of the Kaiser Commission on Medicaid and the Uninsured. "But at the rates costs are rising, even if this effort is very successful, it will do no more than slow the rate of growth."

Among the most frequently excluded drugs are widely advertised, high-priced pills like Nexium and Prevacid for acid reflux, and Vioxx and Celebrex for arthritis pain, for which there are no generic versions yet on the market. Several states report that they save more on acid reflux drugs than any other category; Vermont, a state with half as many people as the Bronx, reports saving more than \$2 million a year on this class of medicines alone. The states allow easy access to a decade-old class of drugs called histamine 2 receptor antagonists that includes Zantac, Pepcid, Tagamet and several generic and over-the-counter variants. But they are restricting access to most of the newer, more expensive class called proton pump inhibitors.

The trend is playing out in thousands of visits like the one a middle-aged woman, suffering from heartburn and acid reflux, recently paid to Dr. John Matthew at his clinic in Plainfield, in central Vermont. She asked for the pills she had seen advertised the night before on television, Dr. Matthew recalled, and not long ago, he would have

written the prescription without a second thought.

Instead, he explained to her that the state of Vermont wanted him to stop prescribing that drug to people on Medicaid and opt for something less expensive. "She understood, and she was fine with it," Dr. Matthew recalled. "And that, somewhat to my surprise, has been the response from almost all our patients."

In fact, in Vermont and a few other states, such programs have been widely embraced, by doctors, consumer groups and others - though not, of course, by pharmaceutical companies. But in other states, Medicaid lists have not been well-received. Patient advocates have even said that a handful of deaths resulted from states' making it too difficult for people to get medicines their doctors thought were appropriate.

Michigan has erected some of the highest barriers to the use of popular drugs and to doctors' deviating from the list of approved medicines. Doctors and patients' rights groups there say that the program sometimes poses a real danger to patients who may not respond to a listed drug or who may be taking other medications that interact with that drug.

Michigan state officials insist that such concerns are exaggerated and that after some growing pains, the program is working well. "We've made the program more responsive, but keep in mind, we've had a lot to overcome," said GERALYN A. LASHER, a spokeswoman for the Michigan Department of Community Health. "A lot of people know the drug they want when they go into a doctor's office, because they've seen that drug very heavily advertised, and that's the newest and most expensive drug, and they walk out of the doctor's office with it unless there's some reason for the doctor to say no."

The pharmaceutical industry has spent heavily on efforts to block the state programs. In the first four months of this year, the industry spent more than \$500,000 on lobbying New York State's Legislature, an increase of more than 30 percent over the same period two years ago, and many prominent lobbyists involved have been working to kill or weaken a preferred drug list bill. The Pharmaceutical Research and Manufacturers of America, the industry lobbying group, has sued unsuccessfully to block the programs in Michigan and Florida.

The industry group did not respond to three telephone messages left last week requesting an interview. But in past statements and in court papers, the group has said that restricting access to prescription drugs means worse health care and that states should be required to win federal approval for their programs.

Prescription drug costs are the fastest-rising part of Medicaid, which is paid for by the federal government, the states and, in some states like New York, by local governments as well. The tab for Medicaid drugs doubled in just four years, reaching \$23 billion last year, and accounted for one of every 10 dollars the program spent on health care.

Unlike many cost-saving plans that appeal mostly to conservatives, the move toward preferred drug lists has cut across ideological lines, as even many lawmakers on the left see it as a way to save money at the expense of big drug companies, not patients.

"This is going to happen in some fashion, so rather than opposing it, I believe we should make sure it happens the right way, with all the needed patient protections," said RICHARD N. GOTTFRIED, the Democratic chairman of the New York Assembly's Health Committee, who has introduced a preferred drug list bill that mirrors Vermont's program.

Included in the budget bills the Legislature enacted last month, over Gov. George E. Pataki's vetoes, was a provision requiring legislation for any preferred drug list program - a measure intended to head off a bid by the Republican governor to establish a strict program on his own.

Several consumer and patient advocacy groups in New York support Mr. Gottfried's bill. But others on the left, including some advocates for the mentally ill and some Democratic legislators, remain opposed to any preferred drug list program, fearing results more like Michigan's than Vermont's. Assemblyman Peter M. Rivera, a Democrat from the Bronx who is chairman of the mental health committee, has predicted that many doctors will settle for less-than-optimal medicines, rather than taking the time and trouble to fight for patients, and that doctors and patients who speak limited English will find it especially hard to navigate a prior approval system.

States restricting the use of drugs under Medicaid have started with a review board that divides the available drugs into "therapeutic classes" - one for heart disease, one for diabetes, one for bacterial infections, and so on. In each class, the panel designates the most effective drugs, usually two per class. Those medicines, and any others that are as affordable or more so, win a place on

the preferred lists, and drugs that cost more are excluded.

Some pharmaceutical companies have offered states new rebates on excluded drugs, lowering the effective price, to get them on the lists.

A doctor who wants to prescribe a drug that is not on the list can petition a state office or a private contractor hired by the state, called a pharmacy benefits manager.

Some states require time consuming phone calls or paperwork for prior authorization, or have difficult procedures for appealing the denial of a drug.

At the other end of the spectrum, in states like Vermont, the phrase "prior authorization" is a misnomer, because the decision always rests with the doctor.

Even so, doctors, pharmacists and state officials say compliance with Vermont's list is very high.

"My shop used to go through about 100 tablets of Protonix a week and 1,500 capsules of Prilosec," said Richard Harvie, a pharmacist in Montpelier, referring to two common acid reflux drugs. "Then, Protonix made the preferred list and Prilosec didn't, and pretty soon it switched to about 30 Prilosec a week and about 1,000 Protonix."