



State Health Watch

Vol. 11 No. 11

The Newsletter on State Health Care Reform

November 2004



Diabetes care in five states is under the microscope; results are mixed

In This Issue

■ How states do — or do not — cover diabetes treatments. It's important to the Medicaid population, study finds cover

■ Oregon's Medicaid waiver saves money. But it appears to have some negative impact on beneficiaries. cover

■ Every night, 2,000 children are in detention facilities even though they've broken no law. Their only crime is they have mental health problems and can't get help 7

■ Medicare will reimburse for treatment related to clinical trials. But there are some things you should know. 10

■ Clip files/Local news from the states 12

The Center for Insulin-Dependent Diabetes Access is monitoring Medicaid coverage for diabetes and has reported on coverage in five states — California, Colorado, New Jersey, Texas, and Washington — chosen for their diversity in size, geographic location, and anticipated range of policies.

The center was created by the Juvenile Diabetes Research Foundation and funded by an unrestricted grant from the Medtronic Foundation. It is staffed by health policy experts from Health Strategies Consultancy LLC.

Health Strategies president Dan Mendelson tells *State Health Watch* it is important to look at diabetes treatment because Medicaid is heavily focused on children and diabetes is a significant childhood illness.

The most vulnerable

“Those who are covered are the most vulnerable in not accessing care properly,” he points out. “They rely on doctors who historically are more responsive to matters of reimbursement.”

See Diabetes care on page 2

Good intentions gone bad? Budget-control waivers cause patient fallout in Oregon

While the federal government and states alike tout the flexibility state Medicaid programs get through use of waivers, a Kaiser Commission on Medicaid and the Uninsured study of the impact of Oregon's Medicaid waiver raises red flags for states to consider as they implement waiver provisions to control Medicaid spending.

**Fiscal Fitness:
How States Cope**

“Like a number of recent waivers, Oregon's waiver included both coverage expansions and reductions,”

the Kaiser analysis said. “However, the waiver agreements between states and the federal government have not required states to move forward with the expansion as a condition of implementing the reductions.

“As such, while a waiver itself may represent a trade-off between expansions and cutbacks, actual implementation can strike a very different balance.”

The study found that while the waiver application predicted 60,000 people would gain coverage through

See Fiscal Fitness on page 4



On-line access / Index

Back issues of *State Health Watch* may be searched on-line for a fee at www.newslettersonline.com/ahc/shw. Issues may be searched by keyword and date of publication.

State Health Watch (ISSN# 1074-4754) is published monthly by Thomson American Health Consultants, 3525 Piedmont Road, Building Six, Suite 400, Atlanta, GA 30305. Telephone: (404) 262-7436. Application to mail at periodicals postage rates is pending at Atlanta, GA 30304. POSTMASTER: Send address changes to **State Health Watch**, P.O. Box 740059, Atlanta, GA 30374.

Subscriber Information:
Customer Service: (800) 688-2421 or fax (800) 284-3291. Hours of operation: 8:30 a.m. - 6 p.m. Monday-Thursday; 8:30 a.m. - 4:30 p.m. Friday ET.
E-mail: customerservice@ahcpub.com.
World Wide Web: www.ahcpub.com.

Subscription rates: \$369 per year. Discounts are available for multiple subscriptions. For pricing information, call Steve Vance at (404) 262-5511. Back issues, when available, are \$58 each.

Government subscription rates: Call customer service at (800) 688-2421 for current rate. For information on multiple subscription rates, call Steve Vance at (404) 262-5511.

(GST registration number R128870672.)

Photocopying: No part of this newsletter may be reproduced in any form or incorporated into any information retrieval system without the written permission of the copyright owner. For reprint permission, contact Thomson American Health Consultants. Telephone: (800) 688-2421.

Opinions expressed are not necessarily those of this publication. Mention of products or services does not constitute endorsement. Clinical, legal, tax, and other comments are offered for general guidance only; professional counsel should be sought for specific situations.

Vice President/Group Publisher:
Brenda Mooney, (404) 262-5403,
brenda.mooney@thomson.com.

Editorial Group Head:
Lee Landenberger, (404) 262-5483,
lee.landenberger@thomson.com.

Managing Editor: **Alison Allen**, (404) 262-5431, alison.allen@thomson.com.

Editor: **John Hope**, (717) 238-5990,
johnhope17110@att.net.

Senior Production Editor: **Ann Duncan**.

Copyright ©2004 Thomson American Health Consultants. All rights reserved.

THOMSON
AMERICAN HEALTH
CONSULTANTS

Diabetes care

Continued from page 1

Center staff noted in their report that they are concerned that diabetes coverage can fall victim to state efforts to cope with budget problems, and coverage limitations can be a particular concern for the more intensive insulin management services, which are more expensive and typically are targeted toward Type 1 diabetes.

Barriers to the best treatment

"Some states have set up barriers to kids getting what the government says is the best treatment for them," Mr. Mendelson declares.

For that reason, the center is monitoring policies that define accessibility to and reimbursement for Type 1 diabetes management treatments and supplies in select Medicaid programs. Specific services for the monitoring include insulin and insulin syringes, blood glucose monitors, testing strips, lancets, insulin pumps (with corresponding infusion sets), and diabetes education and/or case management programs.

Ensure access to care

"As states continue to try to find new ways to control Medicaid spending, it is vital that we keep an eye on diabetes programs to ensure that access to care is not unnecessarily limited," Mr. Mendelson says.

"This initial report outlines the levels of Medicaid reimbursement for various diabetes services and supplies in five states. It raises a red flag about potentially restrictive practices in Texas and California, and also stresses the importance of diabetes disease management programs in guaranteeing access to care while saving money," he points out.

Since state data on the number of Medicaid beneficiaries with diabetes are limited, the center says it is unclear how many patients with diabetes are eligible for Medicaid benefits. However, because Medicaid provides health benefits to the most needy patients, Medicaid policy plays an important role in terms of patient access for all chronic conditions, including diabetes care, the report says.

The center says it is "conceivable that denying supplies and services to diabetics in the short-term may lead to long-term conditions requiring expensive treatment and management.

"Therefore, ensuring access to diabetes services is critical to successful management of the condition, and could even save state Medicaid funds in the long-term. By identifying both positive and negative Medicaid policies and programs in terms of beneficiary access to Type 1 diabetes services, the center can create strategies to encourage states to adopt best practices in terms of diabetes programs and policies. We also can identify harmful policies that stakeholders should attempt to overturn," the organization notes.

Policies haven't been updated

In the five states studied, the report says, Medicaid programs have specific coverage policies for all the diabetes products and supplies researched, but those policies have not changed significantly over the past few years.

Another important factor in terms of patient access to diabetes treatment and supplies is how much state Medicaid programs pay for such services, the report says.

Reimbursement for diabetic supplies through Medicaid generally is adequate for the purchase of

generic products.

However, payment rates are often inadequate to support the purchase of brand-name supplies or high-cost devices with added features. Because Medicaid does not allow beneficiaries to pay the difference between the Medicaid allowance and a charge, beneficiaries only can procure high-cost items if the provider or supplier is willing to accept the Medicaid payment.

“There is some evidence,” the center says, “that Medicaid beneficiaries have reduced access to care, at least partly caused by lower reimbursement as compared to private insurance, but the impact in terms of access to diabetes equipment and supplies is less clear.”

Other points brought up in the report include:

- Insulin and insulin syringes are covered in all five target states and neither requires prior authorization. Restrictions on the frequency and size of insulin refills are left to a prescribing physician’s discretion. The number of prescriptions allowed for insulin syringes in a specific time period is not restricted, although the number of syringes available per prescription often is limited.
- Blood glucose monitors are covered in all five states. While some states require beneficiaries to receive prior authorization before obtaining a monitor, no states have brand restrictions. The reimbursement amount for monitors varies by state; it generally is high enough to cover standard monitors, but inadequate to cover the market price of monitors with additional features such as automatic recording and monitoring features or computer connectivity. There

also are differences in how often beneficiaries are permitted to obtain new monitors.

- All states that were researched cover testing strips without prior authorization. In some states, the amount dispensed per script is restricted by a quantity limit (for example, four boxes a month in Texas), while in other states, beneficiaries receive a certain quantity per script with no limit on the number of scripts per period of time (New Jersey).
- All states cover lancets without prior authorization; and in each state, the amount per script is limited.
- For those states with information publicly available, prior authorization is required for reimbursement of insulin pumps, with the criteria for approval varying. In California, for instance, prior approval for an insulin pump is granted when there is documented frequent and severe glycemic excursions requiring visits to a physician, emergency department, or hospital; demonstrated ability to self-monitor glucose levels four or more times a day; and motivation to achieve and maintain glycemic control. New Jersey does not have specific criteria, but does require prior authorization. Texas requires the following minimum documentation of medical necessity: any wide fluctuations in blood glucose before mealtimes; any dawn phenomenon where fasting blood glucose level often exceeds 20 mg/dL; day-to-day variations in work schedule, mealtimes, and/or activity level that requires multiple insulin injections; and a completed and signed home

health DME/medical supplies physician order form.

- Four of the five target states have or recently had a disease management program for diabetes; New Jersey is the only state without either program. None of the four states with programs have anything specifically for Type 1 diabetes. California’s pilot program was specifically for Type 2 diabetes, while those in Colorado, Texas, and Washington were intended to cover all types of diabetes. California and Washington have moved beyond the pilot stage and include diabetes disease management in their range of provided services directed toward high-cost cases.

Some state policies surprising

“Both Texas and California have coverage policies that are surprising,” Mr. Mendelson explains. “We had to dig to get the policies and it’s hard for a doctor or patient to figure out how to get around them. People are surprised to see that some of these policies are in place and some legislators have told us they’re interested in addressing them,” he adds.

According to Mr. Mendelson, states adopted many of the policies reviewed in the survey for reasons of short-term cost control. But he says there is no evidence that they will control costs in the long term.

Mr. Mendelson says it has taken time for a consensus to develop in the medical community on the best treatment protocols for juvenile diabetes, and it will take a bit longer for Medicaid policies to catch up to the treatment consensus.

[More information is available on the Health Strategies web site: www.healthstrategies.net. Contact Mr. Mendelson at (202) 207-1310.] ■

Fiscal Fitness

Continued from page 1

expansions, in fact, only 2,000 people were added to the rolls, while 50,000 lost coverage.

Oregon's restructuring of its Medicaid program through a Section 1115 waiver and other changes was brought about by serious budget problems and was intended to contain costs and operate the program in ways that parallel commercial health plans, according to the application.

Following the changes, the Office of Oregon Health Policy and Research, with assistance from the Office of Oregon Medical Assistance Programs, established a research collaborative to help inform state and national policymakers about the impact of the changes in the Oregon Medicaid program. That collaborative produced several reports, research briefs, and research presentations that now have been summarized and disseminated by the Kaiser Commission.

Goal not to drop people

Oregon's waiver did not change Medicaid eligibility levels, and its stated intent was not to cut off people from coverage. But the research indicates that in the months following implementation of the waiver, enrollment dropped by about 50,000 people. Those hardest hit had chronic illnesses and other significant health problems.

"Care appears to have been compromised both for those who lost their coverage as well as for many who remain enrolled," Kaiser concluded. "People have been unable to fill prescribed medications, some have had to forgo buying food to afford their copayments, and the number of uninsured patients seeking care through the emergency

room of a major hospital has risen. Many of the research findings are preliminary, and important questions remain unanswered, but the enrollment data and the studies undertaken to date show that the changes have contributed to an increase in the number of uninsured people, compromised access to care, and resulted in new strains on the health care delivery system."

The waiver gave the state authority to make reductions and expansions in coverage, as well as to refinance an existing state-funded premium-assistance program. It permitted the state to reduce benefits, increase premiums and cost-sharing, and cap enrollment for previously eligible poor parents and other adults. It authorized a small expansion for pregnant women and children (from 170% to 185% of the federal poverty level) and a larger expansion for parents and other adults (from 100% to 185% of poverty) — the state only implemented the expansion for pregnant women and children.

In contrast to the expansions, all of the benefit reductions and new beneficiary costs were implemented. The changes were accomplished by dividing people who had been covered by the Oregon Health Plan (OHP) into two different types of coverage: OHP Plus and OHP Standard.

OHP Plus covers children, pregnant women, parents who receive TANF cash payments (below 52% of poverty), elderly and disabled people, and other adults who receive state-funded general assistance welfare payments (below 43% of poverty) who were eligible for Medicaid in Oregon prior to the waiver. It also covers children and pregnant women who became eligible under the waiver expansion (between 170% and 185% of poverty). Because OHP Plus

remains an entitlement program, the state cannot cap or freeze enrollment for eligible individuals. Adults, other than pregnant women, are charged nominal copayments of \$2 to \$3 if they are not enrolled in a managed care plan (most are in managed care). The waiver allows the state to reduce OHP Plus benefits through a new streamlined process without having to seek new waiver authority, and the state has made use of this provision.

Cuts for OHP Standard

OHP Standard covers poor parents and other adults who are not receiving TANF or general assistance, all of whom were eligible for Medicaid in Oregon before the recent changes. Under the new waiver, the state gained authority to cap enrollment for this group, to increase premiums and cost-sharing, and to reduce their benefits.

The ability to cap enrollment permits the state to limit coverage on a first-come, first-served basis rather than based on income or medical need. The state planned to close enrollment July 1, 2004, and new applicants would not be able to enroll. Also, current enrollees who lose their coverage for any reason will not be able to re-enroll.

All OHP Standard enrollees, including those with no income, pay monthly premiums ranging from \$6 to \$20, based on income. The state also has implemented stricter payment policies, including dropping people if they miss one premium payment, not waiving nonpayment for good cause, and making those who are dropped wait six months to re-apply (a provision that becomes moot after the July 1, 2004, permanent end to enrollment). Copayments are charged for most services except preventive care. OHP Standard enrollees can be denied service if they can't afford the

copay. Under a court order, copays were dropped as of June 19, 2004.

Benefits have been reduced significantly below OHP Plus levels, the researchers say. OHP Standard enrollees had no coverage for mental health and substance abuse services, durable medical equipment, and dental and vision services. Prescription drug coverage was dropped by the state legislature in March 2003, but later was restored.

Kaiser's analysis of the research reports found that individuals affected by the waiver had limited incomes and significant health needs. Some of the affected adults had no regular sources of income, while others had incomes just above the cash assistance eligibility levels. And although people who fall into the "disabled" eligibility category were not subject to the benefit, premium, and cost-sharing changes under the waiver, many of those affected by those changes had significant health care needs.

Kaiser said preliminary results from a statewide survey found that almost half reported a chronic condition other than depression or anxiety, such as high blood pressure, asthma, or diabetes, and 36% reported suffering from depression or anxiety.

Thousands lost coverage

The waiver also resulted in thousands of people losing Medicaid coverage, and the majority of those who lost coverage became uninsured. "Although the waiver was advanced as a way to stretch limited dollars to retail and even expand coverage," the report said, "enrollment among those moved into OHP Standard has fallen sharply. In less than one year, the OHP Standard population fell by about one-half — from over 100,000 enrollees in early 2002 to about 50,000 in late 2003. Most of the

change came from disenrollments, although researchers also observed a decline in new enrollments. Preliminary survey results showed that nearly 75% of OHP Standard disenrollees became uninsured."

According to Kaiser's research review, premium increases and stricter premium payment policies appear to be largely responsible for the drop in enrollment. Premiums are not new in Oregon, and all of the adults who were moved into OHP Standard had been charged premiums under the original OHP waiver. Under the new waiver, premium amounts were increased to \$6 to \$20 per month, based on income, and stricter payment policies were implemented.

Researchers have concluded that both the changes in the premium amounts and payment policies, along with some confusion about the changes, contributed to the loss of coverage. Kaiser said Oregon's premium experience was mirrored in Massachusetts, where enrollment declined by 34% to 48%, as a result of new premium charges.

While there were significant Medicaid coverage losses among all those subject to premiums, the study said, the lowest income people experienced the greatest losses.

"Oregon's experience demonstrates how difficult it is for low-income people to manage premiums, even premiums that

appear to be relatively modest," the Kaiser report declared. "OHP Standard covers individuals with incomes below 100% of poverty, and enrollment declined among every income group in OHP Standard. . . . The decline was particularly steep for those at the very bottom of the income scale. More than half (59%) of people with no incomes, who had to pay a \$6 monthly premium, lost their OHP coverage. New enrollments among all income groups also dropped sharply after the new payment policies were implemented. Ten months after implementation, new enrollments for the lowest income group were a little above half the level they were prior to the recent waiver changes."

Access barriers created

The researchers also found that copayments have created barriers to care and reduced access. Physicians in the Portland metropolitan area have reported instances in which people have avoided seeking needed care because of the cost. They report that patients are choosing not to schedule needed follow-up visits, and as a result their health outcomes are getting progressively worse. They also described situations in which patients have stopped taking or have cut back on prescribed medications because they cannot afford to fill the prescriptions.

BINDERS AVAILABLE

STATE HEALTH WATCH has sturdy plastic binders available if you would like to store back issues of the newsletters. To request a binder, please e-mail ahc.binders@thomson.com. Please be sure to include the name of the newsletter, the subscriber number and your full address.



If you need copies of past issues or prefer on-line, searchable access to past issues, you may get that at www.ahcpub.com/online.html.

If you have questions or a problem, please call a customer service representative at **(800) 688-2421**.

One study found that most of those who lost their coverage had an unmet health care need, including some self-reported urgent needs. They were more likely than those who remained in the program to have not filled a prescription due to cost, to report unmet need, and to have unmet mental health needs. Disenrollees also were more likely to identify the emergency department as their usual source of care.

As a result of the waiver changes, the reports said, pressures have shifted to other areas of the health care system. Increases in emergency department visits by uninsured patients have been reported, along with increases in emergency department visits for substance-abuse treatment. There also have been increased pressures on safety-net clinics, and resources for the uninsured have been stretched.

While short-term savings may have been achieved, the researchers said, it was not through premium collections. Before the changes, the state collected about \$900,000 a month in premiums. As a result of lower-than-projected enrollment, premium receipts dropped to about \$500,000 per month by the end of 2003. Kaiser said the state has seen its spending under OHP Standard fall, but that change is due to lower enrollment rather than higher premium collections. At the same time, with a 61% federal match rate, Oregon has had a substantial loss in federal funding for Medicaid.

Although much of the Oregon research is preliminary, the report said, the real-time studies still offer valuable information. Medicaid serves a particularly vulnerable population — people with low incomes, including many with considerable medical needs.

Basic features of the program were designed with such people in mind, and changes to the program's

core elements have significant implications.

“Changes in the Medicaid program, prompted largely by rising costs and the aging population, need to take into account the particular needs of the people served in the program,” the report concluded. “Medicaid beneficiaries have low incomes and generally are in poorer health than the rest of the population. Benefit restrictions and higher costs that people with more income or better health might be able to manage can result in major access barriers, sometimes with devastating results, for the Medicaid population. The early evidence from Oregon suggests the changes that many states are undertaking or considering will likely create a range of new problems with significant consequences for people and the health care delivery system.”

Identifying needed changes

Office of Oregon Health Policy and Research deputy administrator Jeanene Smith tells *State Health Watch* the surveys documented what state officials feared was happening in terms of people leaving Medicaid.

One advantage of the research, she adds, is that it pointed the way

to changes that needed to be made in the program modifications. For instance, mental health and substance abuse benefits were restored for OHP Standard beneficiaries after the research studies demonstrated the heavy reliance those patients had on the services.

Still to be determined, she says, is whether to modify the strict premium payment policies that drop people for nonpayment more quickly than had been the case.

The next biennial session of the Oregon legislature does not convene until January 2005, so no major modifications can be considered until then. Thus, the July 1 deadline for OHP Standard enrollment remained in effect.

Smith says the state recently received a Robert Wood Johnson Foundation grant to expand an emergency department study statewide to get a better handle on utilization. They also are trying to obtain funding for additional waves of the studies that track particular populations over time so they can better determine the impact of the changes on them.

[The report can be downloaded from the Kaiser Commission at www.kff.org. Contact Ms. Smith at (503) 378-2422, ext. 420.] ■

This issue of <i>State Health Watch</i> brings you news from these states:			
California	p. 1	New Jersey	p. 1
Colorado	p. 1	Oregon	pp. 1, 12
District of Columbia	p. 10	Texas	p. 1
Georgia	p. 12	Washington	p. 1
		Wisconsin	p. 9

Experts call for an end to warehousing mentally ill children and teens in juvenile detention centers

“On any given night, as many as 2,000 children and teenagers are languishing in juvenile detention facilities across the country simply because they cannot access the mental health services they need.”

That’s the assessment of a new report that details the growing problem of mentally ill children and youth who are committed to juvenile detention because there are no mental health services available for them.

“These inappropriate detentions are a regrettable symptom of a much larger problem, which is the lack of available, affordable, and appropriate mental health services and support systems for children with mental illness and their families,” says U.S. Sen. Susan Collins (R-ME), who chaired a hearing of the Senate Governmental Affairs Committee.

“When a child has a serious health problem like diabetes or a heart condition, the family turns to their doctor. When the family includes a child with a serious mental illness, it is often forced to go to the child welfare or juvenile justice system to secure treatment.

A crisis that demands attention

“Neither of these systems is equipped to care for a child with a serious mental illness, but in far too many cases, there is nowhere else for the family to turn. It is shocking that so many youth are jailed unnecessarily because they cannot obtain community mental health services. This is a crisis that demands the attention of Congress,” she explains.

The report, prepared by the

House Committee on Government Reform’s Democrat staff special investigations division, presented results from a survey of every juvenile detention facility in the United States to assess what happens to youth when community mental health services are not readily available. More than 500 juvenile detention administrators in 49 states responded, representing some 75% of all such facilities.

Among the findings:

- Two-thirds of juvenile detention facilities hold youth who are waiting for community mental health treatment. These facilities are located in 47 states. In 33 states, youth with mental illness are held in detention centers without any charges against them. And youth incarcerated unnecessarily while awaiting treatment have been as young as 7. Some 117 facilities reported holding children 10 and younger, and a majority of detention facilities reported holding youth younger than 13.
- Over a six-month period, nearly 15,000 incarcerated youth waited for community mental health services.
- Two-thirds of juvenile detention facilities, which hold youth waiting for community mental health services, report that some of these youth have attempted suicide or attacked others. But 25% of the facilities provide no or poor quality mental health services, and more than 50% report inadequate levels of training.
- Juvenile detention facilities spend an estimated \$100 million each year to house youth who are waiting for community mental health

services. That cost estimate does not include any of the additional expense in service provision and staff time associated with holding youth in urgent need of mental health services.

Committee analysts said the survey results likely underestimate the full scope of the problem and major improvements in community mental health services are urgently needed to prevent the unnecessary and inappropriate incarceration of children and youth in the United States.

A 19th century story

At the hearing, U.S. Rep. Henry Waxman, whose staff conducted the survey, said the report “recalls the 19th century, when reformer Dorothea Dix traveled from jail to jail gathering stories of individuals suffering from mental illness who were abandoned and ignored. Her work led to the creation of the nation’s first asylums. Since the mid-1800s, psychiatry and associated professions have learned to diagnose and treat complicated mental illnesses. Hospitalization is now recognized as a treatment of last resort. It is well understood that many children with mental illness can recover and lead productive lives.

“Yet even as scientific knowledge has advanced, our social policy has faltered,” Mr. Waxman said. “We have seen the emptying of psychiatric institutions without the establishment of adequate community services. We have seen the starvation of public budgets that support the basic needs of millions of Americans with mental illness. . . . Congress must ensure that adequate

mental health services are available to all who need them.

“We must reform a confusing and bewildering mental health care system so that it works for the benefit of children and their families. And we must insist upon accountability so that someone is held responsible each and every time a child is jailed to wait for mental health services,” he continued.

National Alliance for the Mentally Ill (NAMI) Maine executive director Carol Carothers told the committee it is hard to imagine a worse place to house a child who requires health care treatment and services for mental illness.

“Surely, we would not dream of placing a child with another serious illness, like cancer for example, in a juvenile detention center to await a hospital bed or community-based treatment,” she pointed out. “It is outrageous that we do this to children with mental illnesses, as young as 7 years old. This takes an enormous toll on the child and the family.”

Corrections officers lack training

Ms. Carothers cautioned that in juvenile detention facilities, the symptoms of mental illness often are misinterpreted by inadequately trained staff as disobedience, defiance, or even threats and often well-meaning but untrained corrections staff respond to such behaviors with anger, discipline, or even force.

“When staff are allowed to resort too quickly to threats and force in the face of noncompliant adolescent behavior,” she said, “minor incidents escalate and the risk of harm increases for both the child and the officer. . . . It is wrong to place children with mental illnesses that require treatment into juvenile detention centers where the symptoms of their illnesses significantly worsen and their long-term out-

comes become much bleaker,” she noted.

“These are environments almost guaranteed to exacerbate their mental illnesses. . . . Additionally, when a child is housed in a juvenile detention facility, parents experience a complete loss of involvement in their child’s life,” Ms. Carothers explained. “The philosophy of many detention centers is to limit contact of youth confined to the facility with their families. Families lack the opportunity to stay closely connected to their child at a time when the child is vulnerable and most in need of their love and support.”

Recommendations

She told the committee the nation is spending money in all the wrong places, and it will be important to appropriate funds to build home- and community-based mental health treatment and services for children with mental disorders.

Recommendations Ms. Carothers made include:

1. Passing the Keeping Families Together Act (S. 1704/H.R. 3243) that would provide grants to eligible states to develop a more comprehensive array of home- and community-based services so families would not have to surrender custody of a child to the state to access mental health services. It also would provide for better coordination among child-serving agencies.
2. Passing additional federal legislation to help improve access to essential community-based services for youth with mental illnesses and their families, including increased funding for the full array of mental health services needed by the youth.
3. Passing the Mentally Ill Offender Treatment and Crime Reduction Act (S. 1194/H.R.

2387) to provide funding for grants to states and communities to be used in a variety of ways to address the high percentage of youth and adults with mental illnesses locked up in jails and prisons. These would include jail diversion programs, community re-entry programs, and enhanced treatment for youth and adults with serious mental illnesses who come into contact with criminal justice systems.

4. Passing the Senator Paul Wellstone Mental Health Equitable Treatment Act (S. 486/H.R. 953) to end discriminatory caps on nearly all private health insurance plans for mental health benefits.
5. Passing the Family Opportunity Act (S. 622/H.R. 1811) to allow families with children with serious disabilities to buy into the Medicaid program on a sliding cost-sharing basis to provide insurance coverage for essential services.

Ms. Carothers tells *State Health Watch* that additional funding to make needed changes is the most important thing Congress could do to be responsive to the concern.

“It would make a big difference, especially given the fiscal crisis most states are facing,” she continues. “Federal grants would help, although that’s not a long-term solution. Ultimately, we need an overhaul of the public mental health system and a revision in the way we look at children in corrections. But that’s a tall order. Mental illness is the only disease where you have to be so sick before you can get help.”

Fixing the system

It’s necessary to fix the juvenile mental health system, according to Ms. Carothers, so the adult system also can be fixed. Many current

policies and procedures, she says, are feeding the adult system with kids.

Despite the magnitude of the problem and of the needed repairs, Ms. Carothers stresses that she has some hope that change can be accomplished.

“Our issues are kind of on the public policy agenda,” she explains. “Because the numbers are so high and the cost is so high, the country may begin to understand the folly of our policies because they’re feeling it in the pocketbook. If they understand the consequences of the policies, maybe they’ll change them.”

Bazon Center for Mental Health Law senior staff attorney Tammy Seltzer told the hearing that detention facility administrators say the children identified for the survey should not be in their facilities and would not be there if appropriate mental health services and supports were available in the community.

Effective alternatives

She said that while model programs still are rare, there are some effective alternatives to incarceration. For example, Wraparound Milwaukee works closely with parents to provide services tailored to the needs of each child so children can stay out of crisis and out of the juvenile justice system.

The program blends funding from the city’s child welfare and juvenile justice agencies and pools it with private and public insurance funds to pay for a coordinated service delivery system.

According to Ms. Seltzer, in its first five years, Wraparound Milwaukee reduced the average monthly cost of care per child from more than \$5,000 to less than \$3,300. And because the savings were reinvested in the program,

program administrators have been able to nearly double the number of children served.

Even more importantly, the ability of the children involved to function at home, in school, and in the community has improved significantly, she continued, and the number returning to the juvenile justice system has been cut in half.

Programs that work

“Fortunately,” Ms. Seltzer testified, “we know the principles that make programs like Wraparound Milwaukee successful in helping children avoid juvenile detention and succeed in their communities. Children and their families must have ready access to mental health services and supports, and this access must be based on kid time, not bankers’ hours. Services and supports must be designed to enable children to succeed at home and school, not just avoid detention.

“Child-serving agencies must be held accountable for serving children well and not rewarded for pushing them off the agency rolls and into the juvenile justice budget. In particular, schools must be responsible for educating and supporting all of their students, and communities must not allow schools to shirk their duties by suspending, expelling, and calling the police on students whose behavior could be effectively addressed using positive behavioral supports. In addition, states and the federal government need to do more to end insurance discrimination and to serve the uninsured,” she told the committee.

Ms. Seltzer tells *State Health Watch* the problem is that parents can’t get the help they need when they need it — they can’t get the kind of help they need to keep their children at home.

“The system focuses on two types of children — at opposite ends of a continuum,” she explains. “It looks at those who don’t need much help and at those who are in full-blown crisis. The system deals with these extremes, but doesn’t do a very good job in the middle. There’s no support to ensure that minor problems don’t escalate to a full-blown crisis. We’re pretty sure at this point that many kids will not need high-end treatment like hospitalization if there are enough supports in place.”

Ms. Seltzer is careful not to blame only the mental health system, noting that the schools have a duty to identify and provide appropriate supports to children with mental health problems so they can learn and be successful.

“There’s not one state that meets the standards set by federal special education legislation,” she adds. “Most schools are resisting applying scientifically proven steps like positive behavioral supports.”

A solvable problem

Speaking emphatically, Ms. Seltzer declares the problem is “absolutely solvable. That’s why reading the congressional report is so frustrating, disappointing, and disheartening. Kids don’t need to end up in the juvenile justice system. It’s solvable at the school level, and it doesn’t cost all that much to create an environment in which children can learn and do well.”

In some ways, she says, reforming the entire mental health system is more challenging than putting things that are proven to work in individual schools, but it also is doable, pointing to the Milwaukee project that she referenced in her testimony.

While Medicaid gives states great flexibility to address the needs of children with serious emotional

disorders through waivers for home- and community-based services, according to Ms. Seltzer, few states have taken advantage of the opportunity.

Waivers for emotional needs

Although 49 states and the District of Columbia have such waivers in place to serve the mentally retarded and those with developmental disabilities, only four states have them for children with emotional problems.

“States that have pursued the waivers find that they are very successful in terms of outcomes and at half the cost,” Ms. Seltzer declares.

She notes one problem is that the waivers can be challenging to obtain because of eligibility rules that require that children to be served need a high-end level of care and would otherwise have to be hospitalized.

Issuing a plea for help

Is Congress listening to the pleas for help? Bazelon Center director of federal relations Laurel Stine tells *State Health Watch* the hearing raised the level of attention paid to the issue. “It raised the attention of other members of Congress, advocates, and the general public.

“We want to help continue to raise awareness that can lead to regulatory solutions to chip away at the problem,” Ms. Stine stresses. “And we hope that Sen. Collins and Rep. Waxman will continue to exercise their leadership.”

[Congressional information is available on-line at www.senate.gov and www.house.gov. Information about specific bills is available on-line at <http://loc.Thomas.gov>. Contact Ms. Carothers through NAMI at (703) 524-7600. Contact Ms. Seltzer and Ms. Stine at Bazelon at (202) 467-5730.] ■

Learn how to navigate the labyrinth of Medicare reimbursement for clinical trials

Medicare and insurer reimbursement in clinical trials is so complex that even the National Academy of Sciences couldn't simplify things. In fact, proposals offered by a task force convened to address the subject five years ago were never adopted.

“The medical leadership had a long series of meetings with the National Institutes of Health (NIH), and the issue was whether or not we could come to a joint agreeable position on Medicare and other insurer coverage of clinical trials,” says John Ludden, MD, director of the MD/MBA program at Tufts University Medical Center in Boston. He was a member of the task force.

“This discussion had many aspects, but what stands out in my mind were a set of proposals that were never adopted by anybody,” Mr. Ludden says.

“The proposal was basically that Medicare should cover clinical trials, and care associated with clinical trials is really the issue, partly because it was absolutely — in my mind — unethical to both get patients into trials as subjects and also to require them to pay for their care,” he adds.

This proposal's most contentious and difficult issue involved non-NIH-sponsored clinical trials, Mr. Ludden notes.

While NIH-sponsored research proposals go through a rigorous scientific review process, the same may not be true for non-NIH trials, he says.

“Would other trials in order to qualify for reimbursement go through a similarly rigorous process?” Mr. Ludden asks. “We

could not agree among ourselves about how that would work and who would pay for the vetting.”

Institutional review boards have become a little tighter in their scientific review in recent years but, nonetheless, there still are real questions about how one would administer this process and how a Medicare officer or officer of another insurer would know that clinical trial X had met the criteria, Mr. Ludden explains.

“The principle that Medicare pays for what it pays for whether or not it's part of a clinical trial still is the watch word,” he says. “In other words, if XYZ is normally paid for by Medicare, it normally will be paid for and not disqualified because the patient is in a clinical trial.”

Appropriate billing required

However, assuring the proper Medicare reimbursement for medical services performed during the course of a clinical trial can be a little challenging.

“I think the evolving story in the area is the continuing concern about the appropriateness of billing Medicare for certain items in a clinical trial,” says Jan Murray, a partner with Squire, Sanders & Dempsey LLP of Cleveland.

“There's concern about whether they're appropriately billing because it's very difficult for the system to determine whether the billing is appropriate or not,” she says. “That's a real concern on the part of academic medical centers.”

During President Clinton's administration, there was a national coverage decision to cover the routine costs of clinical trials, not including the use of investigational

drugs and investigational devices that fall under Category A in which safety and efficacy have not been demonstrated, Ms. Murray notes.

“Category B devices are reimbursed, and the Food and Drug Administration determines which are Category A and Category B for the Centers of Medicare & Medicaid Services [CMS],” she reports. “Most will be Category B devices that have to go through a clinical trial because there’s been a change, and the change doesn’t affect the safety and efficacy of the device.”

For example, there might be an electrical lead on a pacemaker that is being studied, Ms. Murray says.

Standard Medicare coverage

She offers these suggestions for improving Medicare billing compliance during clinical trials:

- It must be a qualified clinical trial. To be eligible for Medicare reimbursement the clinical trial must be qualified under national coverage determination (NCD), Ms. Murray says. “If a trial does not qualify, it may still qualify if it meets several criteria, which is complicated.”

Clinical trials that solely use healthy volunteers are not covered, although if healthy volunteers are included as a control group in a trial studying patients with a disease, then the trial qualifies, she notes.

For example, one issue concerns what is routine care paid by Medicare, Ms. Murray says.

“Routine care is generally anything that is done that would ordinarily be covered under Medicare, so this has to be a trial that would ordinarily go for reimbursement and that is necessary for the health and well-being of patients,” she explains. “And it has to be a service that is normally available to Medicare.”

- Clinical trial monitoring may be excluded. Procedures done solely for monitoring purposes are excluded from Medicare reimbursement, Ms. Murray says.

“If you are doing a test to monitor complications, then it is eligible for Medicare reimbursement,” she explains. “Or if the procedure is to treat or prevent complications, then it is eligible for Medicare reimbursement.”

But items collected solely for data analysis and items that normally are provided free of charge by the hospital are not eligible for Medicare reimbursement, Ms. Murray adds.

“It has to be a qualified clinical trial and generally a clinical trial that provides services ordinarily covered under Medicare,” she says. “It has to have a therapeutic intent.”

- Compliance can be a big issue for hospitals, particularly. “It’s not an easy rule to apply for hospitals,” Ms. Murray says. “This is why there’s a significant compliance issue out there that many hospitals are facing.”

Each clinical trial has its own budget, and that budget combined with the protocol and clinical trial agreement will dictate what the sponsor or grant will finance, she says.

“Under Medicare, you can’t submit a claim for services not covered, and, secondly, you can’t submit a claim that someone else has paid because that’s double billing,” Ms. Murray explains. “So the two biggest concerns are telling what is covered and making sure that someone else has not paid for it.”

One way to determine what’s covered and what might constitute double billing is to look at the clinical trial agreement to see what is covered and what the budget is, she suggests.

“Look at the protocol to determine why something’s being done

and to be aware of what’s communicated to the patient,” Ms. Murray says. “The informed consent process is very important in this too because the informed consent has to include a statement that identifies to the patient what their financial identity is.”

For example, if the informed consent document tells subjects that they or their insurer are not responsible for any costs in the clinical trial, then investigators and institutions cannot bill Medicare for the costs, she says.

“Those three documents: the clinical trial protocol, the clinical trial document, and the informed consent document are very important, and you should look at these for each trial,” Ms. Murray adds.

Other items to note include:

- Which expenses include investigational items or services?
- Which tests are provided solely for data collection or analysis?
- Which sponsor or granting agency is paying for a service, so that an institution does not double bill that item?

Ideally, institutions would conduct this billing compliance process once a month, Ms. Murray says.

Another issue is the flat-rate per-patient charge that may or may not include tests conducted during the course of a clinical trial, she notes.

“It’s important for companies to identify what they’re reimbursing academic medical centers for and to be aware that Medicare does pay for certain things, so perhaps they shouldn’t pay for those,” Ms. Murray says. “But they need to identify exactly what costs they’re picking up to create a clean, non-fraudulent claim.”

- Know the routine costs of a trial. “I think the important thing is for both parties to understand the

routine costs of the trial and what the costs are that are being incurred that go specifically to the cost of the drug or investigational drug, device, or service,” she says. “So if someone is collecting data to analyze the end points, but the data also will give them information about the complication they’re concerned about that relates to safety issue, then it can be hard to distinguish what is reimbursed.”

- Federal auditors are investigating some clinical trials. Medicare concerns are becoming increasingly important and were mentioned in an OIG Workplan, Ms. Murray points out.

“There’s a major investigation that involves the use of investigational devices, and that one resulted in a number of hospitals settling for many millions of dollars,” she notes. “So the feds are aware that this is a potential area of concern for clinical trials reimbursement and investigational device coverage, where there’s a lot of room for error and problems.”

These recent investigations have heightened awareness in the research community, and some institutions have discovered that their main systems for billing Medicare do not accommodate research very well, Ms. Murray adds.

“They’re all scrambling to come up with new ways to deal with this in-house, and that’s a real challenge,” she says.

The best bet for finding out more on Medicare reimbursement would be to contact legal counsel and consultants, including large accounting and financial auditing firms that could provide a billing analysis to determine whether an institution has been handling the Medicare billing properly, Ms. Murray concludes. ■

Clip files / Local news from the states

This column features selected short items about state health care policy.

Two counties to take part in Kid Care health plan

EUGENE, OR—One in five children in Lincoln County, OR, has no health insurance and nearly 50% are living below the federal poverty level or close to it. That’s why Gov. Ted Kulongoski has picked the county, as well as Hood River County, to participate in a pilot project of his Kid Care initiative. As many as 1,500 children in the two counties may be eligible for state health care programs, so state and county officials will work together to reach out to families of uninsured children and get them enrolled in state health insurance programs. “One of my top priorities for Oregon is to ensure all children have access to basic physical and mental health care,” he said in a statement. The state Department of Human Services will support existing coalitions and health care networks in the two counties by providing fliers, posters, and brochures offering training and sending out letters to parents. In both counties, 48% of children and teens live in households with incomes below 200% of the federal poverty level — that’s \$31,344 a year for a family of three. Both counties are already working to identify uninsured children.

—*Eugene Register-Guard*, Sept. 3, 2004

Medicaid overhaul pushed in Georgia

ATLANTA—Georgia plans to move 1 million low-income people on Medicaid into HMO-like organizations — a cost-cutting tactic representing one of the biggest changes in the government program’s history. The plan is being pushed by Gov. Sonny Perdue in response to spending increases of 10% to 12% a year in Georgia Medicaid. The change is necessary “because we cannot sustain the program in its current form,” he said. Some experts said converting 1 million people enrolled in Medicaid to HMOs may cause problems for patients. Currently, these Medicaid recipients are in a fee-for-service system, where they can go to any doctor who accepts Medicaid. The new managed-care plan is expected to begin in January 2006. But other major changes in Medicaid may come sooner. The switch to HMOs would affect about 1 million children, pregnant women, and adults in low-income families in Georgia: 40% of the cost of the state’s Medicaid program, or about \$2.2 billion annually in federal and state funds.

—*Atlanta Journal-Constitution*, Aug. 23, 2004

EDITORIAL ADVISORY BOARD

A. Michael Collins, PhD
Director of Consulting
Services
Government
Operations Group
The MEDSTAT Group
Baltimore

Robert E. Hurley, PhD
Associate Professor
Department of Health
Administration
Medical College of
Virginia
Virginia
Commonwealth
University
Richmond

Vernon K. Smith, PhD
Principal
Health Management
Associates
Lansing, MI