



# Tough NJ law targets office-based anesthesia, holds providers to ambulatory surgery center standards

*Certified nurse anesthetists balk at stricter supervision requirements*

New Jersey regulators are following the shift of health care to outpatient settings with implementation of tough new laws—some say the strictest in the nation—governing office-based anesthesia. With managed care pushing more and more procedures into the outpatient setting, many states may view New Jersey's law as a new benchmark for upgrading their own regulations.

Enactment of the 1998 law caps a 15-year battle during which opponents claimed that regulation of office-based anesthesia would lead to increased health care costs and the closing of some physician practices due to higher overhead.

But it was imperative for regulation to follow the migration of health care services from the hospital to the outpatient settings in order to protect the quality of patient care, says Ervin Moss, MD, executive medical director of the New Jersey State Society of Anesthesiologists in Princeton Junction, NJ.

"I don't worry about the cost; I am concerned about patient safety," says Mr. Moss. He cites examples of deaths that occurred during procedures performed by a physician who administered anesthesia after viewing a 30-minute educational videotape, as well as instances in which anesthetized patients were given intravenous sedation by the office receptionist.

Although Florida and California have had regulations governing office-based anesthesia for three years, New Jersey's regulations are stricter and better defined, says Mr. Moss. "The regulations address standards for training, monitoring equipment, staffing, and credentialing for physicians and staff members administering anesthesia," he adds. (*See story on anesthesia regulations, p. 2.*)

Out-of-date anesthesia machines are a big problem in many physicians' offices, explains Mr. Moss. Typically, a physician will purchase equipment that a hospital is discarding because it is obsolete and

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## ***Model programs aim to get disabled people to work by maintaining Medicaid health benefits***

Expanding Medicaid coverage for the disabled beyond existing income limits will boost their ability to work and simultaneously save the government money.

That's the premise behind three Robert Wood Johnson Foundation model programs in Oregon, Vermont, and Wisconsin. The catch is that most of the money saved is likely to go to federal programs from which the states do not benefit.

While this poses a problem for states, the federal Social Security Administration (SSA) also is funding the concept in hopes of developing a national model that could be rolled out across the country. Wisconsin and Vermont are two of 12 states in a five-year \$25 million SSA grant

program to establish model federal-state incentive programs.

"We want to make sure that those individuals with disabilities who want to work have access to programs that will allow them to do so," Social Security Commissioner Kenneth S. Apfel said in announcing the awards. The grants will help states develop programs of "services and support for their residents with disabilities that will increase job opportunities for them and decrease their dependence on benefits—including Social Security and Supplemental Security Income," he said.

The key to successful work-incentive programs, advocates say, is understanding

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# State Health Watch

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doesn't contain the most recent safety mechanisms, he adds. "The regulations define a safe machine and give physicians six months to update their machines to meet the standards," says Mr. Moss.

This doesn't mean physicians must purchase brand-new equipment, explains Mr. Moss. "A refurbished machine with all of the up-to-date safety equipment costs about \$20,000. When you add the monitors and defibrillator cart, the total comes to \$50,000 to save lives," he notes.

Two other key areas addressed by the regulations include credentialing and reporting of untoward events. Basically, a physician may provide any service in the office that he or she is credentialed to provide in a hospital, explains Moss. If the physician is not credentialed on any hospital medical staff, the regulations describe an alternate credentialing process.

"A hospital has to report untoward events such as an injury, close call, or death that may be related to anesthesia, but we really don't know what has been happening in physicians' offices," says

Mr. Moss. For this reason, he counts the mandatory reporting requirements contained in the regulations as one of the major benefits of his society's efforts.

"We will now be able to collect data and evaluate patient safety related to anesthesia in a physician's office," he explains.

Certified nurse anesthetists who provide anesthesia in an office setting must be certified by the American Association of Nurse Anesthetists in Park Ridge, IL, and be supervised by a physician who meets the criteria to administer anesthesia within the office. The New Jersey Association of Nurse Anesthetists is suing the New Jersey Board of Medical Examiners. The certified registered nurse anesthetists claim that their practice is a nursing practice and should not be supervised by an organization that licenses and oversees physicians. They also claim that their training should allow them to perform anesthesia in an office without anesthesiologist supervision.

Mr. Moss is pleased that the American Society of Anesthesiologists (ASA) in Park Ridge, IL, and the Society of Ambulatory Anesthesia (SAMBA), a sub-

group of the ASA, are looking at the issue of office-based anesthesia. The ASA is developing practice guidelines, and SAMBA is providing education to surgeons, anesthesiologists, and patients through its Web site, says Marc E. Koch, MD, an anesthesiologist in Whitestone, NY, who serves as chairman of SAMBA's Committee on Office-based Anesthesia.

"The numbers and types of procedures performed in office settings has grown rapidly and will continue to grow, so it is important for us to look at how practitioners can provide anesthesia safely," says Mr. Koch.

The guidelines emphasize that there should be one standard of care for all ambulatory anesthetics, whether in a surgery center, doctor's office, or hospital-based ambulatory surgery program, says Rebecca Twersky, MD, president of SAMBA and member of the New York State Task Force on Office Surgery and Anesthesia.

SAMBA members are in the preliminary stages of developing protocols for an anesthesia outcomes study. They also are developing an article that will review

## ***Office anesthesia guidelines modeled after ambulatory surgery regs***

**T**he regulations for office-based anesthesia adopted by the New Jersey State Board of Medical Examiners in Trenton are basically the same regulations governing ambulatory surgery centers, says Ervin Moss, MD, executive medical director of the New Jersey State Society of Anesthesiologists in Princeton Junction, NJ. The regulations spell out exactly what is expected of a physician providing anesthesia services within an office setting in these areas:

### **• Policies and procedures.**

Practitioners are required to have written policies addressing specific procedures performed in the office, responsibilities of staff members providing services, infection control practices, procedures to follow during patients' recovery time, and procedures to follow if a patient experiences complications.

### **• Incident reports.**

Any incident related to surgery, anesthesia, or special procedures that results in a patient's death, transport to a hospital, or complication has to be reported in writing to the Board of Medical Examiners within seven days.

### **• Practitioner standards.**

Physicians may only perform services they are credentialed to perform in a hospital. Physicians also must have a written agreement with a hospital and licensed ambulance service for transport of patients experiencing complications. The law

defines requirements for history and physicals, informed consent, preoperative and postoperative care, and information required for the medical record as well as personnel authorized to perform general anesthesia, regional anesthesia, conscious sedation, and minor conduction blocks.

### **• Equipment.**

Equipment and safety systems required for all locations that provide anesthesia are defined. Examples of equipment required are precordial stethoscope or esophageal stethoscope and a peripheral nerve stimulator, pulse oximeter with appropriate alarms, continuous electrocardiograph with paper recorder, defibrillator, and a respirometer. Locations that provide services to children and infants are required to have emergency equipment and safety devices that are appropriately sized for pediatric patients.

### **• Maintenance.**

Service and maintenance records are to be kept on all anesthesia machines, ventilators, and vaporizers. A daily inspection of equipment is to be performed by the physician or a certified registered nurse anesthetist. Prior to each use, an inspection is to be performed and results documented on the anesthesia record.

*A copy of the regulations is available at no charge from the New Jersey Board of Medical Examiners at (609) 826-7100.*

current literature on office-based anesthesia, state-of-the-art anesthesia technology, legislation regarding office-based anesthesia, and patient safety issues a practitioner should take into account when providing office-based anesthesia.

Mr. Moss says Medicare is forcing more procedures into office settings, such as those requiring only local or regional anesthesia. He also points out that managed care organizations in New Jersey and other states have attempted to limit certain surgical procedures to offices. (*See story on insurance incentive, below.*)

For these reasons, Mr. Moss adamantly maintains that state regulations are the best way to protect patient safety.

"Practice guidelines are helpful, but they are not enforceable, and they are offered as advice only," he says. "Regulations are law, and a physician in New Jersey who doesn't follow the regulations is committing a crime. This is the best way to ensure that any patient receiving anesthesia in an office setting will be safe."

Contact Mr. Moss at (973) 744-8158, the American Society of Anesthesiologists at (847) 825-5586, and the Society of Ambulatory Anesthesia at (847) 825-5586. ■

## ***California officials overhaul outreach efforts for Healthy Families CHIP, MediCal programs***

*More than 1 million children eligible but not insured*

**H**oping to rescue its sputtering children's health programs, California has streamlined its application, increased incentives to processors, and now channels applications into a central processing point. Even so, the state is a long way from enrolling even a fraction of its uninsured children, and still has major hurdles to get over, including how it will treat immigrants.

The state's actions come against the backdrop of a September report by the 100% Campaign, which found that more than one million uninsured California children are eligible for either MediCal, California's Medicaid program, or Healthy Families, the state's Children's Health Insurance Program (CHIP).

At this point, even the state's own goals for CHIP enrollment appear distant. As of November, the state had enrolled about 50,000 of the 400,000

children targeted for enrollment through fiscal 2000.

California's outreach efforts were behind the curve in a number of areas, says Dawn Horner, manager of policy and research for the Children's Partnership, one of the member advocacy groups in the 100% Campaign. Advocates have cited numerous problems, including the complexity of the application, the lack of a central entry point, and how the state has dealt with immigrants who may be eligible for coverage.

The most significant recent change is in the application form for Healthy Families and MediCal. It has been shrunk from an intimidating 28-page document that required a variety of financial calculations to a far simpler four pages.

"Having a form that was 28 pages long seemed to be a deterrent, where individuals would not even try to complete it," says Teri Hodges, spokeswoman

## ***Illinois Blues want to move surgery to office setting***

**I**n Illinois, podiatrists and orthopedists may have a definite financial incentive to offer office-based procedures once a proposal by Chicago-based Blue Cross and Blue Shield of Illinois is enacted.

"We have identified 55 foot and ankle procedures that are already being performed in the office at least 50% of the time, and we have proposed a reimbursement level that recognizes the physician's assumption of additional overhead costs," says Allan Korn, MD, vice president and chief medical officer. Physicians choosing to perform any of the 55 procedures in their office rather than a surgery center will receive a \$200 bonus, explains Mr. Korn.

"Patient safety is our primary concern, so we have asked the Illinois Podiatric Medical Association and the orthopedic surgeons who perform these procedures to review the proposal," says Mr. Korn. He points out that his organization's list of procedures identified within the proposal follows Medicare's site-of-service guidelines.

"To my knowledge, all these procedures require local anesthetic only, but that is one aspect we want local physicians to look at during this review process," adds Mr. Korn.

The Illinois Freestanding Surgery Center Association in

St. Charles, the Illinois Podiatric Medical Association in Chicago, and several groups of orthopedic surgeons have opposed the proposal for a variety of reasons, says Mark Mayo, executive director of the surgery center association.

Not only is there a \$200 bonus paid to physicians who perform the procedures in their offices, but there also is a \$200 penalty for physicians who choose to perform the procedures in an ambulatory surgery center (ASC) or hospital. "This creates a \$400 incentive swing for the surgeon to move the case to the office setting," explains Mr. Mayo.

Several of the procedures on the Blue Cross list—which includes bunionectomies, osteotomies, phalangectomies, tenotomies, and capsulotomies—may require more than local anesthetics, says Mr. Mayo.

"We are concerned about moving cases from regulated settings such as hospitals and ASCs into unregulated settings such as physicians' offices," says Mr. Mayo. The lack of regulation for these settings means a lack of inspection, accreditation, and oversight that ensures patient safety, he adds.

Contact Mr. Korn at Blue Cross and Blue Shield of Illinois, 300 E. Randolph St., Chicago, IL 60601. Contact Mr. Mayo at (630) 584-9801.

for the state Department of Health Services. "A lot of income definitions, a lot of computations" were removed from the application, says Ms. Hodges.

Instead of requiring applicants to figure out the numbers, the state will rely on application assistants—workers with various community organizations where families can apply for the programs—to do the math and understand the eligibility rules. The state has raised the reimbursement to those community assistants from \$25 to \$50 per application as an added incentive for participation, Ms. Hodges says.

Another important change is that families will be able to apply for health coverage for their children without first determining the program for which they are eligible. The streamlined forms will be mailed to a central processing location, where staff will determine whether applicants are eligible for MediCal or Healthy Families, and then channel them into the appropriate program.

"A number of states have had a single point of entry from the beginning of their programs," Ms. Horner notes. Unlike many other states that allow applicants to certify that they're eligible for the programs, California continues to require a large number of documents demonstrating eligibility.

The state also is pressuring the federal government to make it clear that members of immigrant families who apply for the programs will not damage their chances of becoming citizens or resident aliens. This concern also has cropped up, though to a lesser extent, in other states with large immigrant populations, such as Texas and Florida. In California, it is a major stumbling block to signing kids up for coverage.

The children themselves are eligible for health benefits regardless of whether they are citizens. The problem arises when the eligible child is a member of a family of legal immigrants who may seek to become citizens.

If a member of a family is receiving any sort of public assistance—a "public charge," in U.S. Immigration and Naturalization Service lingo—the assistance can complicate other family members' immigration statuses. Parents worry that if they sign their kids up for Healthy

Families or MediCal, they may lose their chance of becoming citizens themselves.

"All the advocacy groups that work with immigrants we've talked to say they don't feel they can tell families to go ahead and apply," Ms. Horner says.

The INS says if the child of an immigrant was born here and is therefore an American citizen, signing up for one of the programs won't affect his or her parents' immigration status. But the agency has not said what the impact would be on families whose children are not citizens.

Some states also have tried to avoid problems with immigration status in its outreach efforts. New York, for example, does not ask the parents of children applying to its Child Health Plus program for their Social Security numbers, and never inquires about citizenship.

Despite the problems, Ms. Horner praises California officials for their

responsiveness to advocates' concerns.

"What California's done that's unique is it's brought the advocates into the program to develop it," she says. California may become even more responsive under new Gov. Gray Davis, Ms. Horner adds.

The 100% Campaign is pushing for expansion of Healthy Families to children in families earning between 200% and 300% of the federal poverty level (about \$50,000 for a family of four in California). During the gubernatorial campaign, Mr. Davis supported an expansion of the program, "although he didn't give specifics," Ms. Horner says. "He said he wanted to use the federal money remaining on the table."

Ms. Horner is referring to the roughly \$2 billion in federal funds for which the state would be eligible but would not have spent by fiscal year 2000, even if the current Healthy Families program were fully implemented. ■

## ***Wisconsin gets ready to collect physician data; medical society proposes consent requirement***

### *Docs fighting innovative program designed to compare costs, outcomes*

**P**assage of a law to collect patient-level data from physicians in Wisconsin was only the first blow. Now comes the real battle as regulators design rules for what appears to be the first comprehensive collection of publicly available patient-level data on physician office visits. The lawmakers want to publish financial and clinical data on physician services for consumers, purchasers, and other health care providers, much as it currently does for hospitals.

The 1998 law that expanded the state's authority to collect the information is intentionally broad. Details will be hashed out in the promulgation of rules in early 1999. Yet, there's enough history and debate to suggest that the state will at least require data on type of procedure, charge, ZIP code, and treating physician.

The State Medical Society of Wisconsin, which fought bitterly to prevent enactment of SB 315, targets "data collection" as one of its 12 priority issues for the legislature's 1999-2000 session. The organization will not try to have the

law repealed, but will reintroduce a proposal to require a patient's informed consent before outpatient data are provided to the state, says Colleen Wilson, medical society legislative counsel.

The medical society is not at all comforted by the fact that the state's nine years of collecting and disseminating patient-level hospital data has not resulted in a breach of confidentiality. Draft rules would require collection of far more data at a finer level of detail than has ever been collected from hospitals, Ms. Wilson says.

A co-sponsor of the bill who defended the legislation through a bruising re-election campaign is ready to fight for it again.

"We should let the law happen," says Gregg Underheim, a Republican representative from Oshkosh. "We will not be dissuaded from implementing the law because of scare tactics which do not address legitimate privacy concerns," he says. Existing provisions that protect the confidentiality of hospital data are

extended to physician data in the new law.

Mr. Underheim claims a large and varied constituency for the bill: the American Association of Retired Persons, Wisconsin Manufacturers & Commerce, the state teachers' union, the AFL-CIO, the National Federation of Independent Businesses, the Coalition of Wisconsin Aging Groups, the Wisconsin Health and Hospital Association, and the Association of Wisconsin HMOs.

Legislators directed the state's Office of Health and Family Services to use the state's emergency rule-making track to implement the law. "We wanted to get it up and running as soon as possible," explains Sandy Lonergan, research assistant for Mr. Underheim. Still, legislators don't expect the process to yield usable data for two to three years.

State officials already can collect patient-level data from hospitals and ambulatory surgery centers. SB 315 brings "healthcare providers," including physicians, under the data-collection umbrella. The information to be collected already is captured on Health Care Financing Administration form 1500 used for Medicare and Medicare billing or the UB-92 used by private payers.

The medical society, which represents about 8,000 of the state's 10,600 licensed physicians, pooh-poohs the notion that physician claims data offer the key to sound decision making. "Simply put, claims data will not tell patients about the abilities of their physicians or the effectiveness of the treatment ordered by a physician for a specific condition," warns a position paper published by the society.

Moreover, the hospital data are notoriously inaccurate and do not set a reliable standard for collection of physician data, Ms. Wilson says.

Wisconsin's attention to physician data reflects an ever-increasing migration of health care services to outpatient settings. Between 1970 and 1996, the proportion of the nation's health care expenditures that went to physician services grew from 18.5% to 19.5%, and is expected to grow to 20.0% by 2007.

While the percentage increase may be modest, it comes simultaneous with a huge explosion of health care expenditures. During the same time period,

health care spending multiplied almost 30-fold, from \$73.2 billion in 1970 to an estimated \$2.1 trillion in 2007. In the September/October 1998 issue of *Health Affairs*, actuaries project that growth in physician expenditures during the next 10 years will come from both public-sector and private-sector spending.

## **Getting disabled people to work**

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the link between health care and employment.

"When we first started talking about this two to three years ago, we would not have looked at employment as where we needed to be devoting our resources," says Jay Wussow, deputy national director of the foundation's Building Health Systems for People with Chronic Illness program. "It took some educating for us to realize that there is this fundamental link between access to the work force and health care. We hope these projects will become national leaders in helping other states with the same issue."

Government health benefits for the disabled typically are tied to eligibility for Supplemental Security Income (SSI) or Social Security Disability Income (SSDI), and the fear of losing them can encourage people to remain on income support even when they might be able to work. Demonstration projects in the Robert Wood Johnson Foundation project help maintain Medicaid coverage for disabled beneficiaries even if they earn incomes too high to remain eligible for federal income assistance. (*For additional information on SSDI and SSI, see related story, p. 6.*)

"We know access to health care is a barrier to getting people employed," says Natalie Funk, a Social Security Administration senior policy analyst who manages work-incentive grants within the SSA's Office of Disability. "Our particular focus is to let states come up with solutions and test them."

A November report from The Presidential Task Force on Employment of Adults with Disabilities targets current federal policies that "punish rather than support" disabled people who are trying to wean themselves off public assistance.

The Wisconsin legislature has appropriated \$250,000 in general revenue to test data-collecting mechanisms. Like the hospitals and ambulatory surgery centers that already give the state data, physicians will be assessed the cost of collection and reporting the information. The law caps the annual physician assessment at \$75. ■

Removing health care and cash benefits before wages can replace the value of these benefits is "contrary to our nation's commitment to protect workers," the report says.

"Health care needs to be supplied for people with disabilities or they'll never seek employment," task force executive director Rebecca Ogle says. She notes that the unemployment rate of adults with disabilities hovers around 70%, and a recent survey of people on SSI and SSDI showed 80% were willing to accept employment if certain barriers were removed.

The Robert Wood Johnson Foundation projects are attempting to address this problem in a way that will allow Medicaid programs to provide essential support services necessary to allow the disabled to work, while not increasing and perhaps even saving net dollars spent.

Vermont's Work Incentive Initiative involves a series of reforms, including a Medicaid buy-in, a relaxing of the income threshold for SSDI beneficiaries, a peer-counseling system, and a focused mental health employment effort. In addition to the Robert Wood Johnson foundation grant, the state has received a five-year, \$2.3 million grant from the Social Security Administration and is seeking waivers from the SSA to relax the SSDI income threshold.

"There's only so much you can do at the state level," says Peter Baird, project director of the Vermont Work Incentives Program. "The real barriers are at the federal level."

The Medicaid buy-in would allow people on SSDI to replace Medicare benefits with the more generous Medicaid package when their monthly incomes exceed \$500. Premiums would cap out at \$40 per month when the person earned

## ***Federal government provides income support for the disabled***

**T**he Social Security Administration administers two income support programs for the disabled: Social Security Disability Insurance (SSDI) and Supplement Security Income (SSI).

SSDI is a program conceptually similar to unemployment insurance in that it is intended to replace the lost wages of a disabled worker. The amount of the award is calculated based on the length of a person's participation in the work force. About 4.6 million disabled workers nationally receive SSDI payments; the average monthly amount is \$722. Participants are eligible to make up to \$500 per month—what the Social Security Administration considers “substantial gainful activity”—before cash benefits are terminated.

After two years of receiving SSDI, a beneficiary receives free Medicare coverage for hospital services and the option to purchase physician coverage. Such coverage generally lasts about three years, after which a person may purchase

Medicare benefits at the same cost an uninsured person would pay.

About 4.3 million adults receive SSI because of a disability. It is need-based, targeted to people who had little or no income before incurring a disability. The Social Security Administration payments to disabled adults on SSI average just under \$400 per month. Most states supplement that amount with an average of around \$110 per month. People who are eligible for SSI also have access to food stamps, and, in most states, full Medicaid services.

The Social Security Administration generally reduces a disabled worker's SSI cash award \$1 for every \$2 in earned income after the first \$85 each month. In an effort to help people return to work, the federal government allows beneficiaries to deduct work-related and other expenses from their income. A person earning too much to receive SSI payments still may be eligible for Medicaid, depending upon the state.

an annual income of \$24,000.

The Balanced Budget Act (BBA) of 1997 already allows state Medicaid programs to include working SSI beneficiaries in families with incomes up to 250% of the federal poverty level. But the BBA does not make any provisions to return some of the cost savings that accrue to the federal government back to state Medicaid programs, so the provision largely has been ignored.

“It saves the federal government money, but it doesn't do jack for the states,” observes Ms. Ogle. Federal legislation that would have rerouted some of the savings from such disability work incentives back to the states (SB 1858) failed in the last session of Congress.

Vermont's peer counseling will try to replicate the “remarkable success” of a similar program among the chronically unemployed in the state's vocational rehabilitation program. “We found that the big problem for them was social isolation. Within six months [of the start of the program], 80% percent of them were employed,” Mr. Baird says.

The mental health initiative implements a team approach to care delivered through community mental health centers and places an employment specialist on each treatment team. The Dartmouth College model on which the initiative is based saw the employment rate of a

group of mental health patients rise from 7% to 25% over a five-year period.

The big snag at this point is securing federal approval to allow Vermont SSDI beneficiaries to earn more than \$500 monthly without losing their cash benefits. Vermont wants the Social Security Administration to reduce SSDI cash awards to working people gradually, \$1 for every \$2 earned over the threshold. The state also needs federal approval to guarantee that people who participate in the project and try to work won't lose their benefits if they opt for conventional disability benefits later, Mr. Baird says.

Congress has let lapse the legislative authority that would allow the SSA to grant that kind of flexibility. Renewal of that authority was part of a sweeping package of employment and disability reforms contained in the failed Work Incentives Improvement Act (SB 1858), sponsored by Sens. Jim Jeffords (R-VT), Ted Kennedy (D-MA), and Tom Harkin (D-IA). The Presidential Task Force in its November report endorsed the Jeffords-Kennedy provisions that would expand Medicare and Medicaid for the disabled who attempt to return to work.

Without the guarantee of future benefits, Vermont will not enroll people in the program. Other program officials say the guarantees are crucial to the success of any disability employment initiative.

“What we don't want to do is get in this gotcha game,” says Doug Stone, co-director of the Oregon Employment Initiative. “If you have a benefit based on the fact that [a person] can't work, there's a fear of saying, ‘Now, I want to work.’ What if it doesn't work out?”

State officials in Oregon, in an amendment to their Medicaid plan, took advantage of the Balanced Budget Act to raise the annual SSI income eligibility threshold from \$20,000 to \$40,000. For those employees who are lucky enough to land jobs with health benefits, state officials are exploring ways to continue Medicaid coverage for services employer plans don't cover. Employer-sponsored health benefits typically are leaner than Medicaid, particularly for services such as those from a personal care attendant. Attendant services often are indispensable for people with disabilities—regardless of whether they are in the work force—and can cost \$1,500 to \$2,000 per month.

“There's a fear that a person with disabilities may drive up health care costs. What we want to do in Oregon is create a public-private partnership to help address those concerns,” Mr. Stone says.

*Contact Mr. Wussow at (619) 279-0700, Mr. Stone at (503) 945-5836, Mr. Baird at (802) 241-2127, and Ms. Ogle at (202) 219-6081. ■*

# Settlement in pharmacy price-fixing case means cash back to low-income residents

*Community health centers to coordinate distribution of \$64.3 million*

The working poor in 10 states and the District of Columbia will receive a portion of the settlement from a \$64.3 million price-fixing suit against brand-name pharmaceutical firms.

The National Association of Community Health Centers (NACHC) is coordinating the distribution of the settlement through community health centers and similar entities in Arizona, the District of Columbia, Florida, Kansas, Maine, Michigan, Minnesota, New York, North Carolina, Tennessee, and Wisconsin. The federal centers are open to all residents, but use a sliding scale fee schedule and other mechanisms to target their services to the poor. The jurisdictions in the suit are home to 300 of the nation's 654 federal centers.

"It's a wonderful approach with respect to money to be distributed," said plaintiffs' attorney Bernard Persky,

a partner in the New York City law firm of Goodkind, Labaton, Rudoff & Sucharow LLP. "We're concentrating the benefit to the people who need it most."

The agreement has been approved by courts in eight states and the District of Columbia. Settlement agreements are scheduled in January for North Carolina and in February for Tennessee. Net awards among the states range from about \$700,000 to \$7.1 million (see chart below).

The suits—which are virtually identical but separate in each jurisdiction—charge that about 30 drug manufacturers have fixed drug prices for retail pharmacies higher than those offered to hospitals, health maintenance organizations, and mail-order drug companies. The burden of those higher prices, the suits say, fell largely on those who buy prescriptions directly from pharmacies and the uninsured.

Community health centers in individual states will apply for funds to the NACHC and will be restricted in how they distribute the settlement by a few broad guidelines. Settlement cash is available only to non-Medicaid patients. Centers will not be able to supplant existing subsidies for pharmaceuticals. The benefit, like all services at community health centers, must be available to all people regardless of income, including those who are well-off.

In all jurisdictions but the District of Columbia, anyone receiving the benefit must be a patient of the participating health center. The limited number of health centers in the District of Columbia prompted the court there to require only that a person contact the center but not necessarily enroll as a patient. In the District of Columbia and Kansas, the courts added a small number of clinics other than federally qualified health centers to those eligible to distribute funds.

Community health centers in Arizona, Michigan, and Wisconsin have gotten together to develop methodologies for distribution of the settlement in their respective states. In Arizona, for example, 13 organizations will apply separately for a predetermined figure based on their level of non-Medicaid care. For the remaining areas, NACHC will evaluate individual applications, and, if requested amounts exceed what is available, allocate the settlement on a pro rata basis, says NACHC executive vice president Claudia Gibson.

While association and community health center officials applauded the award, it pales in comparison to what pharmaceutical firms already are able to donate to community health centers. Pfizer, one of the defendants named in the suit, contributed \$145.4 million in drugs to community health center patients between 1993 and November 1998. Through its Sharing the Care program with the NACHC and the National Governors'

## Settlements in Class Action Price-fixing Case

| State                | Approximate Net Settlement Amount |
|----------------------|-----------------------------------|
| Arizona              | \$5,886,930                       |
| District of Columbia | 4,848,060                         |
| Kentucky             | 3,809,190                         |
| Florida              | 6,233,220                         |
| Maine                | 692,580                           |
| Michigan             | 2,216,256                         |
| New York             | 1,385,160                         |
| Minnesota            | 1,385,160                         |
| North Carolina       | 6,233,220                         |
| Tennessee            | Not available                     |
| Wisconsin            | 7,133,574                         |

Figures represent 70% of total settlement and reflect 25% attorney's fees, 1.1% fee to the National Association of Community Health Centers, and other expenses.

Source: Goodkind, Labaton, Rudoff & Sucharow LLP, New York City.

Association, Pfizer estimates that it donated 2.9 prescriptions each to 890,000 people though more than 360 health centers.

Ms. Gibson estimates that federally qualified health centers serve about 10 million people nationally, 70% of whom are women and children. About two-thirds of the centers' patients are not on Medicaid and therefore are eligible for

the settlement benefit. About half of the centers' patients—or three-fourths of those eligible for the settlement benefit—are uninsured, Ms. Gibson says.

The jurisdictions in the class-action suit were chosen because laws in these areas allow individual purchasers to receive compensation in a price-fixing suit of this nature, Mr. Persky explains. In other areas, prevailing law gives that

right to the so-called "direct consumer," the retail pharmacy.

Contact Mr. Persky at (212) 907-0868 and Ms. Gibson at (202) 659-8008.

Details of the progress of the settlement in each jurisdiction are described on the Internet at [www.rxconsumerlit.com](http://www.rxconsumerlit.com). When distributions of the settlement begin, technical assistance will be available at (800) 790-8476. ■

## Emergency service providers seek to expand scope

*Look for paramedics in primary care, public health roles, especially where resources are scarce*

Emergency medical services are looking for a shot in the arm. They hope to get it by delivering immunizations, providing primary care, and taking on expanded triage responsibilities. For many communities, the shift in orientation better reflects what residents need, and the fact that a huge portion of so-called "emergency medical service" does not call for lights and sirens.

"Our whole system is tied to moving people. What we're finding out is that's not always a good idea," observes Barak Wolff, chief of New Mexico's emergency medical services (EMS) bureau.

### EMS to become fully integrated

Instead, EMS systems are refashioning themselves as front-line providers, particularly for rural or underserved communities. The next century's EMS system will be "fully integrated with the overall health care system" and will "contribute to the treatment of chronic conditions and community health monitoring," according to an EMS agenda for the future published in the February 1998 *Annals of Emergency Medicine*. The consensus document, three years in the making, was commissioned by the National Highway Traffic Safety Administration in cooperation with the Health Resources and Services Administration.

The challenge for EMS has been to win the recognition and reimbursement that comes with the additional responsibilities. The more spectacular gains have been in smaller or relatively isolated communities.

The snow-skiing resort of Red River in north-central New Mexico has it all—great slopes, restaurants, nightspots—but, until recently, there was no physician. Of necessity, EMS providers there became what the local fire chief calls "closet primary care providers." By the early 1990s, though, chief Ron Burnham saw an opportunity to improve the quality of his system. Supported by grants and working with health care providers 40 miles away in Taos, he developed a curriculum to teach paramedics the basics of primary care, public health, and triage.

### Giving poor customer service

"Before, we had two choices," says Mr. Burnham. "We could load them into an ambulance and take them to a hospital emergency room, or get a signed refusal of care if they didn't want that. Well, that's not very good customer service."

Now, when people present to the EMS system, one of four scenarios unfolds:

1. The patient is transported by ambulance.
2. Paramedics take a medical history, and, at the scene, contact either the system medical director or the patient's own doctor for further direction.
3. The patient is evaluated, given some "temporizing therapy," and referred to follow-up care.
4. The patient is managed by a paramedic without referral to or immediate consultation with a physician. Charts of all the patients in this fourth category undergo chart review by a physician.

Although Medicare and Medicaid do not pay for non-transport EMS care, fees from direct patient billing and some third-party payers are enough to cover the program's modest personnel and training costs, Mr. Burnham says.

The response from the community has been "overwhelming," says Mr. Burnham, raising the daily number of calls from one or two to 18 to 20. "And from a medical point of view, it's been safe," he says.

"Our whole system is tied to moving people. What we're finding out is that's not always a good idea."

Barak Wolff

The very success of the program may have slowed its growth. After a beefed-up EMS system made it less scary to be a solo practitioner in Red River, the community of 500 permanent residents secured a few hours each week on the schedule of a primary care physician in July of 1998. Mr. Burnham says it's "fine" that the number of daytime calls to EMS has declined somewhat since then. He maintains his system isn't in competition with other providers; the real concern now is making sure the tiny town is ready for the 12,000 winter residents who flood the area.

"The success of the program usually is dependent upon the availability of local resources," says American Ambulance Association administrative director Mike Harmon. "Where local resources are scarce, these projects seem to do better." Mr. Harmon's Sacramento, CA-based association generally supports the development of so-called "expanded scope" emergency medical services and has developed training material to instruct EMTs and paramedics on basic primary care and similar services.

### Testing assessment skills

When the proportion of uninsured patients grew to about 30% of their transports, officials with Rural/Metro Medical Services of Central New York in Syracuse looked for a way to reduce the load and improve care. Beginning in early 1999, paramedics specially trained in assessment skills, while continuing to operate as usual, will document instances in which they would have treated and referred the patient to follow-up care. Rural/Metro expects the trained paramedics to match the judgment of a physician panel at least 90% of the time as well as outperform colleagues without such training.

The additional training is designed to give paramedics the skills to recognize and treat nonemergency conditions that can be stabilized until a visit to a physician the following day. For example, earaches alone account for between 800 and 1,000 of the system's 32,000 transports annually, says Mike Addarrio, general manager of Rural/Metro.

The catch is that no one is offering to pay for such services, at least not yet. Rural/Metro picked up the \$50,000 tab for the study and hopes to get the attention of Medicaid and managed care officials with the results, which are due in late 1999.

Unlike New Mexico, where state law specifically allows EMS systems to make a case for an expanded paramedic scope of care, New York limits the flexibility of paramedics to triage care at the scene. State regulations require that EMS systems honor a request for transport to a hospital, even when it does not seem to be clinically indicated, Mr. Addarrio says.

All Jan Warfield wanted from her local fire department in Austin, TX, was a place to hold an immunization clinic. The outreach coordinator with the state's Division of Immunization thought the idea couldn't miss—the bells, fire trucks, maybe even bunker gear would attract kids like a magnet.

"Once I started talking to the paramedics, I realized they could give the shots themselves," says Ms. Warfield.

Now she's sold on the idea. Austin's 38 firehouses provide convenient and safe places to hold the clinics, and the site is certainly a lot more fun than a health department clinic. Similar efforts are under way in Corpus Christi and Harker Heights, she says.

"It is the most effective, efficient approach to patient care, and at some point, Medicare, Medicaid, and insurance are going to realize it."

Nick Waters

The fire departments are not paid to provide immunizations, but the clinics provide another way for the fire department to document its value to the community, Ms. Warfield says.

Officials in Orange County, NC, are convinced their efforts are saving local taxpayer dollars, even though Medicare and Medicaid don't recognize the \$100 charge for their non-transport treatment and referral services. Reducing the number of transports during the last two years has allowed the county-owned system to avoid about \$800,000 in the costs of buying, equipping, staffing, and housing two new ambulances, says Nick Waters, the county's director of emergency management.

The county uses paramedic-staffed sedans when a careful screening of the call suggests there is no need for haste. A system of fire trucks and ambulances for first response and transport still are in

place for emergency calls, but the use of lights and sirens has decreased 80% under the new protocols.

"We will roll lights and sirens on those calls where response time makes a difference. Most of the time it doesn't make a difference," Mr. Waters says.

### Using 12-hour shifts

The Orange County system also is rethinking the traditional 24-hour shift, which assumes paramedics will nap or relax between calls. Shifts are 12 hours long, but they're full. Between calls, for example, paramedics may visit the homes of new parents to provide safety and health information as part of the system's "Welcome to the World" program. The effort has been very successful not only in providing care but also in getting the community used to paramedics in a nonemergency role, says Mr. Waters.

Clinical outcomes improved since the new triage system was implemented in the fall of 1996, with the county's out-of-hospital save rate on cardiac arrests rising from 6% to 20%. Orange County's treat-and-release protocols for nonemergency care free up ambulances and skilled personnel to better respond to the most critically ill in the community, Mr. Waters says.

The county began billing Medicare, Medicaid, and private payers for transports when it restructured operations. Officials are using the new revenue to offset the costs of the nonemergency sedans, additional equipment, and contracts with local volunteer squads to staff a slimmed-down ambulance schedule.

"It is the most effective, efficient approach to patient care, and at some point, Medicare, Medicaid, and insurance are going to realize it," Mr. Waters says. ■

# North Carolina's talking about my generation: The kids are alright, but they'll need help soon

It's 1999—do you know where your boomers are? North Carolina officials can say yes, thanks to a recent profile of residents born between 1946 and 1964. The report gives policy-makers a heads-up on how to prepare for the boomer assault, while debunking some popular misconceptions about the soon-to-be-elderly.

For example, the report by the state's Division of Aging notes that boomers generally are considered to be well-educated. North Carolina's boomers stayed in school longer than their parents did, but by the time they were 25 to 34, fewer than half had a high school education. Their education "limits the occupational potential of the boomers and makes lifelong learning a necessity," notes a division report.

"We can't wait until they're of retirement age to provide them opportunities to learn new skills," says Dennis Streets, director of planning and information

for the division.

Granted, some 36% of North Carolina's community college population in 1996 was made up of boomers, but Mr. Streets worries that these are boomers who have had the learning bug all their lives, not folks stepping back after a 20-year hiatus.

North Carolina boomers in the profile lived up to the stereotype of being more affluent than their parents, but that is due in large part to the greater proportion of two-income families.

Physically, North Carolina boomers are a disaster. They exercise less than older state residents or boomers in other parts of the country. About 28% have no health insurance, leaving state officials to worry about these people's health status when they hit retirement age.

The report also noted the "great diversity" of family arrangements of North Carolina boomers. They are less likely

than their parents to be living in married head-of-household families or with parents, and more likely to be living alone, as single heads of households, or with a partner to whom they are not married.

North Carolina officials have good reason to worry about the impending boomer crunch. While those 65 and older accounted for 12.8% of the population in 1998, that proportion is expected to grow to 21.4% by 2025.

State officials are holding regional forums to explain the ramifications of the aging of the baby boomers to North Carolina's residents, businesses, schools, and other institutions. The state is still in the "very early stages" of the process and hopes to expand its efforts with particular attention to financial issues such as pensions and the Social Security system, Mr. Streets says.

Contact Mr. Streets at (919) 733-3983. ■

## Clip file / Local news from the states

*Each month, this column features selected short items about state health care policy digested from publications from around the country.*

### Texas suit challenges legality of financial incentives HMOs give to physicians

AUSTIN, TX—Health maintenance organizations' financial incentives for physicians violate state laws against incentives for limiting care, according to three suits filed by Texas Attorney General Dan Morales against six managed care plans in mid-December.

Observers say the action is the largest taken against the managed care industry in state history.

Aetna owns four of the six plans named: Aetna U.S. Healthcare, Aetna Health Plans of North Texas, NYLCare Health Plans of the Southwest, and NYLCare Health Plans of the Gulf Coast. Also named in separate suits are Humana Health Plans of Texas and PacifiCare of Texas.

All three companies denied the accusations and said they were surprised by the suits because they had been discussing the contracts with Morales' office for several months.

In August, the Texas Department of Insurance settled a similar complaint against Harris Methodist Health Plan, a large north Texas HMO. In a consent order, Harris agreed to rewrite contracts and to reimburse physicians.

"We cannot allow the accountants and lawyers at the HMOs to make decisions about what is proper medical care for patients," Mr. Morales said in a prepared statement. "That is a decision reserved for patients' doctors, and those doctors should not be manipulated by the HMOs."

The suits are being brought under a 1997 state law that forbids HMOs from using any "financial incentive" or "payment . . . that acts directly or indirectly as an inducement to limit medically necessary services." The suits ask that the companies be fined and prevented from continuing the practices.

The defendants also are accused of providing members with deceptive or untruthful information regarding coverage for emergency services, prescription drugs, and referrals to specialists as well as misrepresenting the timeliness of handling claims.

—*Dallas Morning News*, Dec. 17; *Fort Worth Star-Telegram*, Dec. 16

### Washington State gets the help of pharmacists to expand access to emergency birth control

SEATTLE—Washington State pharmacists wrote 2,765 prescriptions for emergency contraception in the first four months of a project encouraging access to the drug through pharmacist collaborative agreements.

A study published in November/December *Family Planning Perspectives* calls the response to the project “overwhelmingly positive.” One major pharmaceutical chain that previously had averaged about one prescription for emergency contraception per week filled an average of 61 per week during the project. About 500 pharmacists at 111 pharmacies participated in the initiative.

Washington is one of 22 states that allow pharmacists to prescribe drugs under collaborative agreements with a “prescriber,” a physician or nurse practitioner. By August 1998, the Washington Board of Pharmacy had approved 117 protocols specifying the conditions under which treatment can be provided. Washington law is relatively liberal and does not place any restriction on the type of drug or location of practice.

The authors conclude that pharmacists can play an important role in increasing access to emergency contraception and note that as many as 14 states have legislation “favorable” to establishing prescriptive practice agreements.

—*Family Planning Perspectives*, November/December 1998

### **Lost in the Medicaid managed care shuffle, public health struggles to regain its footing**

WASHINGTON, DC—Medicaid managed care largely has ignored the nation’s public health departments as providers of primary care and other services, thus draining the departments of both patients and revenues. In response, many of the nation’s 3,000 city and county public health departments are de-emphasizing the delivery of services in favor of a return to traditional public health activities such as health promotion or investigating community health problems, concludes a recent issue brief published by the Center for Studying Health System Change in Washington, DC.

The study also found the following:

- Some health departments are pursuing cooperative arrangements with Medicaid managed care plans. Unfortunately, most of these contractual arrangements lack clarity about the role of the health department. Where there is clarity, two models are emerging: reimbursing local health departments for Medicaid services, even outside the formal managed care networks; and requiring Medicaid managed care plans to collaborate with local public health departments on specific services such as infectious disease control.

- Rarely do the states set specific requirements for comprehensive involvement of the public health departments. Some state contracts are more likely to spell out a role for local health departments on a service-by-service basis, particularly infectious diseases. In California, for example, the state contract specifies that tuberculosis patients requiring directly observed therapy be referred to the local health department.

- States have not been as active as they could have been in clarifying a role for health departments in a privatized Medicaid system, but some health departments are finding their own way by developing formal and informal relationships with Medicaid managed care plans. Without such direction, health departments that are more aggressive about partnering

with managed care plans can better ensure their place in the local health care system.

The study, *Public Health Departments Adapt to Medicaid Managed Care*, was written by Rose Marie Martinez and Elizabeth Closter. The Center for Studying Health System Change is funded exclusively by the Robert Wood Johnson Foundation and is affiliated with Mathematica Policy Research.

—Center for Studying Health Center Change, excerpted from Issue Brief #16, November 1998

### **CDC recommends name reporting for HIV infection but wants states to keep anonymous testing**

ATLANTA—Public health officials should report the names of people with HIV in their surveillance efforts in the same way they now collect the names of persons with AIDS, the Centers for Disease Control and Prevention recommended in draft surveillance guidelines released Dec. 10.

The guidelines recognized a “greater sensitivity” of HIV case surveillance data compared to AIDS data alone, and said it was “essential” for surveillance programs to strengthen their data-protection efforts. They note that, as of July 1998, 32 states were conducting HIV case surveillance using the same methods as those for AIDS surveillance.

The expanded use of name reporting, according to the guidelines, will allow public health officials to better understand the prevalence and incidence of HIV, particularly among ethnic minorities. However, the CDC supports the continued availability of anonymous testing. The agency “strongly recommends” the repeal of state and local laws prohibiting anonymous testing, “given the overriding public health objective of encouraging knowledge of HIV serologic status.”

While not binding on states, the guidelines, if adopted, would represent a “gold standard” with regard to HIV and AIDS surveillance practices. The guidelines can be found on the CDC Web site at [www.cdc.gov/nchstp/hiv\\_aids/dhap.htm](http://www.cdc.gov/nchstp/hiv_aids/dhap.htm).

—*Federal Register*, Dec. 10

### **Certificates of Need may control long-term care costs now, but what about the long run?**

WASHINGTON, DC—Controlling the supply of nursing homes might serve the ends of the industry and state regulators now, but “it is unclear how well this strategy will work over the long run,” concludes a 13-state analysis of Certificate of Need laws completed by The Urban Institute in Washington, DC.

States should turn their attention to alternatives to institutional long-term care, which have taken advantage of “minimal government regulation” to become a growing part of states’ Medicaid and long-term care spending, the report says.

The report notes that home health has eased the pressure for long-term care in the face of limited nursing home availability but questions how long this alternative will be available.



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The report concludes it is important for state officials to anticipate future long-term care needs and develop the services to meet them. "The care needs of the elderly do not disappear just because no nursing home beds or home health agencies are available," conclude the authors of *Controlling the Supply of Long-Term Care Providers at the State Level*.

Researchers studied the nursing home industry in Alabama, California, Colorado, Florida, Massachusetts, Michigan, Minnesota, Mississippi, New Jersey, New York, Texas, Washington, and Wisconsin.

—A copy of the report is available on the Internet at <http://newfederalism.urban.org/html/occ22.html> or by contacting The Urban Institute at (202) 261-5709.

**Editorial comments or questions?**

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