STATE NEWS

FDA DECISION ON PLAN B TOSSES THE BALL TO STATES

Christina Kent

The Food and Drug Administration’s (FDA) recent decision on Plan B doesn’t resolve the controversy over emergency contraception. To some extent, it puts the ball in states’ courts.

The only emergency contraceptive approved by the FDA to prevent pregnancy after contraceptive failure, unprotected intercourse and/or rape, Plan B has been available by prescription since 1999. On Aug. 24, the FDA ruled that Plan B will be available over the counter (OTC) to adults at least 18 years old with proof of age. Minors will continue to need a prescription.

The fact that Plan B will be available OTC to some and to others by prescription raises some thorny issues for states, touching on Medicaid, access for persons who are not in Medicaid and the “collaborative practice” arrangements that eight states have put in place and others are considering.

The debate could grow heated in some legislatures next year. Michigan Rep. Barb Vander Veen backs a bill (HB 5311) that would go beyond the FDA ruling by requiring a prescription for the dispensing of an emergency contraceptive to anyone of any age. “I think that the medical and psychological ramifications (of using emergency contraceptives) are not clearly understood,” she said. “I feel much more comfortable having a medical professional explain [the issue and options to a patient]...The fear of an unplanned pregnancy is real, and women will suffer without a real understanding of their choices.”
Others say that Plan B should be more available because it lowers the number of abortions and unplanned births that occur in the United States. About half of the six million pregnancies that take place in the U.S. each year are unintended, and about half of those end in abortion, according to the Alan Guttmacher Institute. Women who have unintended pregnancies are less likely to seek prenatal care and have low-birthweight babies, said Christina Tenuta, program coordinator of NARAL’s Emergency Contraceptive Access Campaign. Furthermore, research shows that access to emergency contraception does not decrease women’s willingness to use regular birth control.

Plan B works like a birth control pill, preventing pregnancy mainly by stopping the release of an egg from the ovary. It is possible that Plan B also may work by preventing fertilization of an egg or by preventing implantation, which usually begins seven days after release of an egg from the ovary, the FDA says. If taken within three days of unprotected intercourse, the pills reduce the risk of pregnancy by 89 percent.

Barr Pharmaceuticals, which manufactures Plan B, and some advocacy groups asked the FDA to make the drug available OTC on grounds that doing so would help women obtain it within the critical 72-hour time period and save (especially) uninsured, low-income women a costly trip to the doctor. Opponents such as Concerned Women for America argue that OTC status will encourage teens and others to have unprotected sex, resulting in more unwanted pregnancies. They also liken the pills to abortion, because they could prevent a fertilized egg from being implanted.

Expected to retail at $20 to $40, Plan B should be available OTC before the end of the year, after Barr prepares an educational campaign and new packaging.

Prescriptions for OTC Products

According to Barr, the Plan B decision marks the first time a product will be available in the United States both over the counter and by prescription. This dual status “throws a wrench into the works” for Medicaid, said one state official.

Under federal rules, state Medicaid programs must cover all prescription products sold by manufacturers that have signed a drug rebate agreement with the federal government (although states can restrict coverage through formularies and prior authorization). Nearly all states also cover some OTC products, generally with prior authorization. State officials have found that covering such products produces major savings in certain areas, such as in the treatment of allergies and sinus problems.

In order to get a federal match for drugs, devices and services, federal rules require that they be “medically necessary.” Many states have found it convenient to require prescriptions for the OTC products that they want to provide to their Medicaid populations because the prescription shows that the product is medically necessary, and the “paper trail” produced by the prescription enables authorities to control utilization and expenditures.

Under the FDA’s ruling, state Medicaid programs may continue supplying Plan B to minors with a prescription. States that want to cover Plan B for their adult Medicaid beneficiaries may choose to require a prescription for what would otherwise be an OTC drug—or they may choose to take no action, which could limit access for adult Medicaid beneficiaries who cannot afford to pay out-of-pocket for the drug.

West Virginia Medicaid plans to continue to cover Plan B for adults, said a spokeswoman for the state Department of Health and Human Resources. “We’re certainly not going to
yank it because it’s available over the counter to uninsured women,” she said. The big question is how to go about adding the prescription requirement: by amending the state Medicaid plan or through some other mechanism.

**Utah** Medicaid currently reimburses providers for two prescriptions for Plan B, after which the enrollee must agree to adhere to some form of birth control. State legislators, of course, can overrule any decisions made by their Medicaid agencies. Utah Sen. Allen Christensen doubts that the Legislature will alter any decisions made by the administration. “We think the family ought to be the one to deal with such matters,” he explained. “It’s so difficult to get any kind of (legislated) change at all.”

**Beyond Medicaid**

Under federal law, states may place more restrictions on access to any FDA-approved product than the FDA has. For example, many states have required pharmacies to limit the sale of OTC cold products that contain pseudoephedrine, a main ingredient in methamphetamine. But states may not remove any FDA stipulations on products by, for example, allowing drugs that are prescription-only to be available OTC.

Some states are considering actions that would go beyond the boundaries of Medicaid. As noted above, a Michigan bill would require a prescription for all sales of emergency contraceptives. **HB 5311** was introduced in 2006, and its chief sponsor, Rep. John Stahl, hopes to advance the measure in 2007, said Jamie Hope, Stahl’s staffer. The representative’s biggest concern is that pedophiles will obtain the drug OTC and give it to underage girls in order to prevent their becoming pregnant, she said. “It’s going to give predators another avenue to carry out their crimes,” she said. “We’re just trying to protect our women and children.”

Fear that pedophiles will use Plan B to carry out their crimes is “just not realistic,” said Tenuta. “We have never seen it happen.”

**Increasing Access**

Eight states have taken steps to make Plan B more easily accessible to their residents. **California, Hawaii, Maine, New Hampshire, New Mexico, Vermont** and **Washington** each have authorized collaborative practice agreements that enable pharmacists to provide emergency contraceptives to patients without their having to first visit a physician, according to Kirsten Moore, president of the [Reproductive Health Technologies Project](http://www.reproductivehealthtechnologies.org). In any of the eight states, women who are younger than 18 can obtain Plan B simply by meeting the protocol agreed to by the pharmacist. “The FDA decision will not affect these agreements at all,” Moore said.

There are two basic models for the agreements, she added. In Washington, the pharmacists partner with physicians, who delegate prescribing authority under a specific protocol. In California and in most other states, she said, the state delegates the authority to the pharmacist and outlines the protocols that the pharmacist must follow in order to prescribe (and fill) that prescription.

The [Pharmacy Access Partnership](http://www.pharmacyaccesspartnership.org) notes that authority for the practice agreement is usually incorporated into the state pharmacy practice act, generally within the definition section that describes the authorized scope of practice.
THE ROLE OF FAMILY PLANNING

Family planning services have long been a staple of Medicaid programs because:

- a 1972 federal law mandates that states fund pregnancy-related care, including family planning services, for 60 days postpartum to women with incomes up to at least 133 percent of the federal poverty level;
- the federal government provides a generous 90 percent federal match for such services; and
- a large body of research shows that access to family planning greatly reduces the number of unplanned pregnancies and abortions, and protects the health of mothers and babies by allowing women to control the time between births. The federal Healthy People 2010 report estimates that every $1 invested in family planning saves $3 in costs that Medicaid would otherwise pay for pregnancy and newborn care.

At least 24 states have found reproductive services to be so beneficial that they’ve obtained waivers to extend Medicaid eligibility for family planning services to individuals who would otherwise not be eligible. California’s Family PACT program is regarded as particularly successful, as are programs in South Carolina, Oklahoma and other states.

STATE NEWS

CALIFORNIA COURT BLOCKS CHANGES IN DRUG TREATMENT LAW

Matthew Gever

Legislation that would put more teeth into California’s drug court system has been temporarily blocked by a lawsuit.

Signed into law in July, the legislation (SB 1137) amends Proposition 36, a ballot initiative passed by California voters in 2001. Also known as the Substance Abuse and Crime Prevention Act of 2000, Prop. 36 allows nonviolent drug offenders to choose treatment as an alternative to jail.

The new law would amend Prop. 36 by adding “flash incarcerations” as punishment for those not adhering to the program. This would allow judges to impose short jail sentences—ranging from two to five days—on offenders who violate treatment. The bill also provides increased funding for the program, as well as increased judicial supervision of clients.
The new law came from a “broad consensus” of drug court officers, judges, probation officers, district attorneys and public defenders who were seeking ways to make Prop. 36 more effective, said Sen. Denise Ducheny, sponsor of SB 1137. “It was working as we hoped for those who participated,” she explained. “Our concern was to figure out how to make Prop. 36 more accountable and get more people through the program.”

But opponents of the new law said it changed the intention of Prop. 36. “Being placed in a county jail does not mean you are getting anything that helps you,” said Sen. Sheila Kuehl.

Brought by the Drug Policy Alliance and the California Society of Addiction Medicine, the lawsuit contends that the new law violated the original intent of Prop. 36 and that the Proposed changes needed approval from the voters.

Superior Court Judge Winifred Smith ruled that the legislative changes are at odds with the original purpose of the law. The court issued a preliminary injunction blocking implementation of SB 1137, saying it would create “a probability of harm to the public, both in terms of expenditures that Proposition 36 apparently meant to prevent, and in terms of potential incarceration of persons that Proposition 36 apparently meant to avoid.” The court also expressed concern that the will of the voters was ignored, supporting the plaintiffs’ argument that only another initiative could legally amend the original law.

Under Prop. 36, offenders in treatment must report to a probation officer, a case manager and a treatment officer. If treatment is completed, the court may expunge the charges. A violation such as testing positive or missing a meeting can result in arrest and being sent back to court. Three violations means an offender must serve out his or her jail term.

Sen. Ducheny did not comment about what actions may be taken if the law is ultimately struck down by the courts. She did note, however, that the bill contains a clause stating that if any part of SB 1137 is banned, the bill will be placed automatically on the ballot for a vote.

Savings and Recidivism

This year marks the fifth anniversary of Proposition 36, which California voters passed in 2001 with 61 percent of the vote. It was the second state to pass a treatment-in-lieu-of-incarceration initiative, following Arizona’s Proposition 200 in 1996. In 2002, Washington, DC voters passed Measure 62, an initiative similar to those in Arizona and California.

Earlier this year, researchers at the Integrated Substance Abuse Programs at UCLA’s Geffen School of Medicine released a cost-benefit analysis of Prop. 36. According to the study, Prop. 36 achieved a cost-benefit ratio of 2.5, meaning $2.50 was saved for every dollar spent in the first year of the treatment program. In the second year, the program produced savings of $2.30 for every dollar spent. That adds up to taxpayer savings of $140.5 million in the first year and $158.8 million in the second year. Most of those savings are from reductions in jail and prison terms.

However, the news is not all rosy. Only 24 percent of enrollees completed treatment, which is on the low end of the average for all treatment programs, according to Doug Marlowe, director of law & ethics research at the Treatment Research Institute. Sixty percent of those diverted end up having their parole revoked, which includes 30 percent of those diverted who never show up for treatment in the first place. Additionally, recidivism rates increased under Prop. 36, according to Marlowe, whose research contributed to SB 1137.
Marlowe said that “flash incarceration” would make California’s program more closely resemble other states’ drug courts, which give judges increased flexibility in determining rewards and punishments, including jail time. In a press release issued in support of the legislative changes, Marlowe wrote, “In other jurisdictions, evaluations have shown the traditional drug court model, which the California initiative will now resemble, reaps savings far in excess of the investment, as better treatment outcomes lead to fewer arrests and incarceration costs, lower health-care utilization and reductions in other costs the public bears when substance abuse is not effectively treated.”

"The cost savings are dramatic, but with increased system accountability measures and improved offender management, as well as incentives to community programs for better treatment entry, retention and completion rates, they could rise even higher," said UCLA study co-author M. Douglas Anglin.

**HIGHLIGHTS**

**ACCESS**

**Cover Tennessee**

**Tennessee** Gov. Phil Bredesen on Sept. 18 released details of the state’s new children’s health insurance and drug assistance programs. [Cover Kids](#) and [CoverRX](#), both of which will begin in January 2007, are part of the governor’s [Cover Tennessee](#) initiative. Cover Kids will be available to children younger than age 19 who have been uninsured for at least three months and to pregnant women who meet certain eligibility criteria. Eligible residents will pay income-based premiums, with no premiums for enrollees with annual incomes of less than 250 percent of the federal poverty level. Those enrollees will pay $5 for prescription generic drugs, $20 for prescription brand-name drugs, $15 for physicians' visits, $50 for emergency department visits and $100 for hospital admissions. There will be no co-pay for laboratory work, x-rays or ambulance services if the care is medically necessary. Officials hope to enroll 75,000 of the state's 130,000 uninsured children in CoverKids over the next three years. CoverRX will provide prescription drug coverage to state residents who are uninsured or do not have drug coverage under their insurance plans. Participants will contribute income-based copays, with individuals with annual incomes of up to 250 percent of the poverty level paying no more than $10 for generic medications and $15 for brand-name drugs. Coverage will be limited to five prescriptions—not including insulin, diabetes supplies and some mental health medications—at one time. The program will offer coverage for about 250 medications.

**Premium Increases Slow**

For the first time in six years, the rise in employer-sponsored health insurance premiums has slowed. In 2006, premiums increased an average 7.7 percent, compared with increases of 9.2 percent in 2005 and 13.9 percent in 2003, according to a report released Sept. 26 by the Henry J. Kaiser Family Foundation and the Health Research and Educational Trust. Researchers surveyed 3,159 employers between January and May of 2006. They found that in 2006, premiums increased at more than twice the rate of employee wages and overall inflation. Since 2000, workers' contributions rose 84 percent, while their incomes increased 20 percent and inflation rose 18 percent. In 2006, about 4 percent of employees were
enrolled in high-deductible plans linked to health savings accounts or health reimbursement arrangements. Despite the slowdown in premium hikes, “We are still losing the race between premiums and workers' earnings, and if that trend persists, employer-based coverage will continue to decline as fewer employers and workers can afford the cost of coverage,” report co-author Jon Gabel told the Kansas City Star. The full survey is available online.

PUBLIC HEALTH

**Testing Guidelines**

States may want to adopt or modify new guidelines on HIV testing from the Centers for Disease Control and Prevention. Published in the Sept. 22 Morbidity and Mortality Weekly Report, the guidelines urge that HIV tests become a routine part of medical care for residents ages 13 to 64 and that requirements for written consent and pretest counseling be dropped. The CDC estimates that about 25 percent of HIV-positive people in the U.S. do not know their HIV status, and many physicians believe that routine testing could lead to earlier diagnosis and earlier treatment, the New York Times reports. Many states currently require that individuals participate in a 20-minute counseling session before undergoing an HIV test. In addition, people in some states must sign a separate informed-consent form, which details the risks and benefits of the test. The revised guidelines say providers do not have to require written consent forms or undergo counseling, but physicians must allow patients to opt out of the test. It also is “essential” that physicians provide HIV-infected patients with links to clinical care, counseling, support and prevention services. Some advocacy groups oppose removing the pretest counseling requirements, fearing that providers will not give patients information that can enable them to avoid putting themselves and others at risk. The AIDS Project Los Angeles questions who will pay for increased testing costs. “This mandate would require at least an additional $6 billion, yet the federal government has cut domestic funding for care, treatment and services over the past five years,” Craig Thompson, executive director of APLA, told the National Journal. “Conducting millions of HIV tests without appropriating the money for follow-up care is an empty promise.”

**Infant Mortality/Life Expectancy Rates**

Among almost two dozen industrialized nations, the United States has the highest infant mortality rate and lowest life expectancy rate for residents older than age 60, according to a report posted Sept. 20 on the Web site of the journal Health Affairs. Researchers for the Commonwealth Fund’s Commission on a High Performance Health System examined 37 indicators of health outcomes, quality, access, equity and efficiency developed by the Institute of Medicine, the U.S. Department of Health and Human Services, the Agency for Healthcare Research and Quality, the National Committee for Quality Assurance and other experts. Overall, the U.S. scored an average 66 out of a possible 100 on the health indicators and did not score highest on any of the indicators, according to the report. The report also found that one-third of U.S. patients reported a medical, medication or laboratory error within the past two years; only 17 percent of U.S. physicians use electronic health records, which can prevent medical errors; and, about 115 per 100,000 deaths in the U.S. are preventable with proper health care, compared with 75 in France and 81 in Japan.
**INJURY PREVENTION**

*Suicides Outnumber Homicides*

Suicides account for three times as many violent deaths as homicides in **Connecticut**, says a study released Sept. 20 by the Injury Prevention Center at **Connecticut Children’s Medical Center**. The study examined 108 homicides and 296 suicides in 2004, comparing the race, ethnic background and gender of those who died violent deaths. The study showed that there were three times as many suicides in 2004 as homicides. Suicide victims were overwhelmingly male, white and most likely died of gunshot wounds and strangulation. The study found that black men, age 20 to 24, were eight times more likely than any other group to die as the result of homicide. Report authors hope the results will encourage the creation of statewide violence and suicide prevention efforts. Connecticut spent $7.6 million in 2004 treating victims of gun violence, 80 percent of whom were Medicaid recipients or uninsured.

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**GRAPHICALLY SPEAKING**

**ADULT OBESITY CONTINUES TO GAIN**

As part of their *Healthy People 2010* objectives, the **Centers for Disease Control and Prevention** (CDC) set the goal of reducing the prevalence of obesity among adults in the United States by 15 percent by the year 2010. However, according to the CDC, both national-level data from the National Health and Nutrition Examination Survey (**NHANES**) and state-level data from the Behavioral Risk Factor Surveillance System (**BRFSS**) indicate that the prevalence of obesity among adults continued to increase during the past decade, from 11.6 percent in 1999 to nearly 24 percent in 2005 (see table below).

Meanwhile, a Sept. 18 report from the **Institute of Medicine** (IOM) finds that the many obesity prevention programs targeted at children and youth that are in place are fragmented and small-scale. Furthermore, systematic monitoring and evaluation of prevention efforts is lacking, as well as a mechanism to disseminate and apply lessons learned. The report recommends that federal, state and local governments establish high-level task forces to identify priorities for action and to coordinate public-sector efforts. Secondly, policymakers are urged to evaluate existing prevention programs, and develop and implement improvements. A third recommendation urges governments at all levels to develop new surveillance systems, while increasing funding for obesity prevention research. Finally, the IOM recommends releasing information on evaluations of childhood obesity policies and interventions. It suggests that the federal government provide incentives and rewards to state and local government agencies to coordinate efforts that improve outcomes for children and youth. To read the report, click [here](#).
### TABLE. Percentage of adults aged ≥18 years who were obese, * by demographic characteristics — Behavioral Risk Factor Surveillance System, United States, 1995, 2000, and 2005

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>1995 (n = 110,352)</th>
<th>2000 (n = 172,157)</th>
<th>2005 (n = 223,730)</th>
</tr>
</thead>
</table>
|               | % (99% CI)
|               | % (99% CI)         | % (99% CI)         |
| **Total**     | 15.3 (14.8–15.7)   | 19.8 (19.4–20.2)   | 23.9 (23.5–24.2)   |
| **Mon**       | 15.0 (14.9–16.4)   | 20.2 (19.6–20.9)   | 24.2 (23.6–24.8)   |
| **Women**     | 14.9 (14.3–15.5)   | 19.4 (18.8–19.9)   | 23.5 (23.1–24.0)   |
| **Age group (yrs)** |       |                    |                     |
| 19–29         | 10.2 (9.3–11.1)    | 13.5 (12.7–14.4)   | 17.7 (16.7–18.7)   |
| 30–39         | 14.3 (13.4–15.3)   | 20.2 (19.2–21.1)   | 24.4 (23.5–25.3)   |
| 40–49         | 17.9 (16.7–19.0)   | 22.9 (21.8–23.9)   | 26.5 (25.4–27.6)   |
| 50–59         | 21.5 (19.6–23.5)   | 25.6 (24.4–26.8)   | 29.5 (28.6–30.4)   |
| 60–69         | 19.4 (18.0–20.8)   | 22.9 (21.5–24.2)   | 28.1 (27.1–29.0)   |
| ≥70           | 12.2 (11.1–13.2)   | 15.5 (14.4–16.5)   | 18.3 (17.5–19.1)   |
| **Race/Ethnicity** |     |                    |                     |
| Non-Hispanic white | 14.5 (13.4–16.0) | 18.5 (18.0–18.9) | 22.6 (22.2–23.0) |
| Non-Hispanic black | 22.7 (21.7–23.7) | 29.3 (27.9–30.8) | 33.0 (32.5–33.5) |
| Hispanic<sup>2</sup> | 16.8 (15.6–18.0) | 23.4 (21.9–24.9) | 28.5 (27.9–29.1) |
| Other          | 9.7 (7.6–11.8)     | 12.0 (10.3–13.8)   | 16.0 (14.4–16.7)   |

* Persons with a body mass index (BMI) of ≥30.0; self-reported weight and height were used to calculate BMI (weight [kg]/height [m]^2").

<sup>1</sup> Confidence interval.

<sup>2</sup> Might be of any race.