get age of the CDC recommendation is 64 years, the only people for whom Medicare would cover screening are the 6.8 million current beneficiaries under age 65 who qualify by disability, Ms. Lubinski said.

Thus, the bulk of the reimbursement for HIV screening would fall to Medicaid, which currently provides health coverage to about half of all people with AIDS in the United States and a significant number of those newly diagnosed with HIV. In an analysis done in 25 states, 22% of HIV-infected individuals were already Medicaid eligible at the time of diagnosis.

Federal law allows HIV screening to be covered by states either under fee-for-service or Medicaid managed care, but this service is "optional." A recent study by George Washington University's Center for Health Services Research and Policy found that Medicaid programs in 32 of the 48 states surveyed covered targeted HIV testing and counseling. A few state programs also covered services such as HIV risk assessment and case management.

But as yet, with the exception of New Jersey, most state Medicaid programs have not adopted routine HIV testing. California has employed a special waiver to provide broad family planning services including HIV testing and counseling for men and women of childbearing age up to 200% of the poverty level. However, that type of waiver is unlikely to be granted elsewhere, she noted.

States could opt to cover HIV screening under a "diagnostic, screening, preventive, and rehabilitative" (DSPR) benefit. The state would need to broaden the definition of medical necessity to allow for preventive services such as HIV screening, as Massachusetts has done. There, a service is "medically necessary if it is reasonably calculated to prevent, diagnose, prevent the worsening of, alleviate, correct, or cure conditions in the member that endanger life, or cause suffering or pain."

Such definitions could theoretically make HIV testing and counseling eligible for reimbursement, Ms. Lubinski said.

She said she believes the federal government must contribute more to Medicaid to implement the CDC guidelines, noting: "It is absolutely unreasonable to think that the modest amount of discretionary funding through the CDC, Ryan White [Comprehensive AIDS Resources Emergency Act], or state and local health departments [will] be adequate. … Medicaid, with its significant reach into low-income populations and ethnic/racial minorities, must be part of the financing mix. Federal leadership could and should facilitate coverage of routine screening by state Medicaid programs." ■

Device Safety Monitoring to Get Tune-Up

The Food and Drug Administration has announced that it is taking steps to improve its postmarketing surveillance of medical device safety, including moving ahead on a proposal to require electronic reporting of adverse events.

The agency said it has created an action plan based on a major review that was completed in 2005. That review looked at how the Center for Radiological Devices and Health (CDRH) handles recalls and enforcement actions against manufacturers that are not in compliance with FDA rules.

The report "details a number of action items that we believe will transform the postmarketing safety program," Dr. Daniel Schultz, director of CDRH, said in a briefing with reporters.

The FDA will focus on improvements in four major areas: collaboration among experts within CDRH, data systems, communications with patients and physicians about risks and benefits, and enforcement.

CDRH leaders will encourage more cross-organizational collaboration so premarket, postmarket, and enforcement efforts are better coordinated, he said.

Some of the biggest changes will come in data collection and analysis. The agency hopes to integrate its passive adverse events reporting system (Manufacturer and User Facility Device Experience Database, also known as MAUDE) and its active system, the Medical Product Safety Device Network (MedSun), Dr. Schultz said. Currently, 350 hospitals have been trained to report device problems on MedSun. One goal is to recruit more facilities and upgrade reporting so it is closer to real-time.

The agency also hopes to require manufacturers and others to electronically report adverse events. Currently, FDA receives about 200,000 reports to MAUDE each year, and most are on paper, which delays entry into the system and analysis for safety signals, Dr. Schultz said. The FDA has been piloting an electronic reporting program, and is writing a rule to require electronic reporting, he said.

Once data are being reported and analyzed more quickly, enforcement will be more timely also. This will let the FDA focus enforcement efforts on the highest-risk products, Dr. Schultz said.

—Alicia Ault