CMS Rule Change May Cut Coverage for Children

BY ALICIA AULT
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The true impact isn't known yet, but an administrative change by the Centers for Medicare and Medicaid Services to rules governing the State Children's Health Insurance Program—made on a Friday night during Congress' August recess—may have the effect of dropping children who currently have coverage.

Sen. Jay Rockefeller (D-W.Va.), one of the coauthors of SCHIP, sent a letter to President George W. Bush chiding the administration for making the change without congressional input.

"Not only do I question the wisdom and legality of this new policy, I also question the process," he wrote, noting that "a policy change of this magnitude should, at a minimum, be handled through the formal rulemaking process, with proper public notice and comment, and not through unilateral subregulatory guidance."

About 4 million children are eligible for Medicaid or SCHIP currently; some 6 million received benefits in 2006. An estimated 9 million children do not have health insurance.

SCHIP, now entering its 10th year, has been the subject of fierce battles this year, as lawmakers have struggled to agree on financing for the next 5 years. Authorization for SCHIP expires Sept. 30. Before leaving for summer recess, the House and the Senate passed vastly different funding packages. (See box.)

President Bush said he would veto either bill, saying that he viewed both as a back-door way of expanding government-financed health care at the expense of the private insurance market.

So, the Aug. 17 letter from CMS Director for Medicaid and State Operations Dennis G. Smith to state health officials should not have come as a surprise. In the letter, states were told that if they were raising eligibility for children whose family incomes were equal to or above 250% of the federal poverty level, they would have to meet stringent new requirements. The goal: to ensure that these families aren't opting for SCHIP instead of private insurance. "Existing regulations … provide that states must have 'reasonable procedures' to prevent substitution of public SCHIP coverage for private coverage," wrote Mr. Smith.

Many states have had such procedures in place, but the CMS is now requiring that specific processes be implemented. For instance, children will have to be uninsured for at least 1 year before receiving SCHIP benefits. Currently, only Alaska requires a yearlong exclusion, said Judy Solomon, a senior fellow with the Center on Budget and Policy Priorities, a Washington-based policy research organization. Most states have a 1- to 6-month waiting period, but many have generous exceptions to those rules.

With the administrative change, states also will have to prove that they've enrolled at least 95% of children who are below 200% of the federal poverty level, and document that the number of low-income children who are eligible for and covered by private insurance has not dropped by more than 2% in the past 5 years. States that have already increased their eligibility to 250% or more—18 states—will have to comply with the new requirements within a year or lose some of their federal matching funds.

The CMS said the requirements should not harm children who currently receive benefits. But although it's not clear how many might be dropped, "At the very least, you're going to have thousands of children unable to get coverage," Ms. Solomon said.

SCHIP was designed to give states flexibility to meet the needs of their own citizenry, she noted. But the new policy is diminishing that flexibility. "This turns back the clock," said Ms. Solomon.

The House and Senate will meet in conference in September to determine the course of SCHIP over the next 5 years. ■

Senate, House Bills Differ

In August, the Senate overwhelmingly passed S. 1893, which includes a $35-billion increase for SCHIP. The funds would come from an increase in the federal tobacco tax.

The approved House legislation (H.R. 3162), on the other hand, contains a number of provisions unrelated to SCHIP. For example, it would halt next year's planned 10% cut in the Medicare physician fee schedule, instead putting in place a 0.5% increase for 2008 and another for 2009.

In terms of SCHIP funding, the House bill calls for a $50-billion increase in funding and would pay for it with increases in the federal tobacco tax and cuts to subsidies given to Medicare Advantage plans.

The House bill also outlines a new physician payment structure under Medicare that would set a separate conversion factor for six service categories: evaluation and management for primary care and for other services, imaging, major procedures, anesthesia services, and minor procedures.

The proposed formula would also take prescription drugs out of the spending targets and take into account Medicare coverage decisions when setting targets, according to Rich Trachtman, American College of Physicians legislative affairs director. But the formula would still lead to deep payment cuts starting in 2010, so there is an understanding the updates for 2010 and beyond would require additional action, he said.

But the American College of Cardiology expressed problems with the House bill's new structure for Medicare payments. The structure would be based on a system of separate expenditure targets that would not take into account the appropriate growth in services, including many common cardiovascular services, the ACC asserted. "While the ACC appreciates congressional efforts to stop Medicare physician payment cuts, it is critical that any new payment structure is fair to all physicians," it said in a statement.

The bill would also waive cost sharing for Medicare beneficiaries for certain preventive services, including cardiovascular screening blood tests and diabetes screening tests.

—Mary Ellen Schneider

House Panel Eyes FDA Leniency in Wake of Warning to Stent Maker

BY ALICIA AULT
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The U.S. House Committee on Energy and Commerce is looking into whether the Food and Drug Administration may have been too lenient in its treatment of Cordis Corp. after the agency warned the company in 2004 about manufacturing violations relating to its Cypher sirolimus-eluting coronary stent.

In letters sent to FDA Commissioner Dr. Andrew von Eschenbach and to Johnson & Johnson CEO William Weldon in August, the congressional committee said it was seeking all documentation relating to FDA inspections of six Cordis facilities in 2003.

Following those inspections, the agency sent a warning letter to Cordis, a Johnson & Johnson subsidiary, in April 2004 citing violations in good manufacturing practice regulations. The FDA found "systemic violations in the quality management system employed to ensure the safety and effectiveness of your drug-eluting stents that recurred at several of your facilities," wrote the agency in its warning letter.

"Despite these numerous violations, however, Cordis was allowed to continue marketing Cypher stents," wrote Committee Chairman Rep. John Dingell (D-Mich.) and Oversight and Investigations Subcommittee Chairman Rep. Bart Stupak (D-Mich.).

Companies are legally entitled to continue manufacturing a drug or device after a issuance of warning letter. If there is a public health threat, the agency will seek a voluntary recall. Otherwise, until the violations cited in a warning letter are resolved, a manufacturer can't receive approval of other new or pending applications for drugs or devices. For Cordis, that hold lasted from April 2004 until June 2007.

In an interview, Ira Loss, an analyst who follows the medical device and pharmaceutical sectors for Washington Analysis Corp., noted that Cordis lost ground to competitors that had carotid stents approved while its carotid device was on hold. He said it was not clear why the Energy and Commerce panel would be pursuing an action against Cordis now.

The first half of 2007 has been a dismal one for drug-eluting stents. When compared with the second quarter of 2006, U.S. sales of Cypher dropped 41% in the second quarter of 2007, to $210 million, reported Johnson & Johnson. Sales outside the United States dropped 30%, to $240 million. ■

Part D, Medicare Advantage Plan Changes Proposed by CMS

Officials at the Centers for Medicare and Medicaid Services are proposing changes to the Medicare Part D prescription drug plans and Medicare Advantage plans to strengthen oversight of the programs.

The proposal includes mandatory self-reporting aimed at curbing potential fraud and misconduct by plans. It also includes changes to streamline the process of intermediate sanctions and contract determinations, and it clarifies the process for imposing civil money penalties.

"While the majority of Medicare Advantage and Medicare Prescription Drug Plans that offer important benefits to beneficiaries are conducting themselves professionally, it is important for CMS to be able to take swift action to safeguard beneficiaries from unlawful or questionable business practices," Leslie Norwalk, acting CMS administrator, said in a statement.

But the Bush administration is falling short in policing the marketing practices of Medicare Advantage plans, said Robert M. Hayes, president of the Medicare Rights Center. He has called on Congress to establish clear safeguards against "abusive and deceptive" marketing practices and to give state governments the power to enforce those standards. He also called for the establishment of minimum benefit standards and standardized benefit packages to allow for better consumer comparison of plans.

Officials at the American Medical Association are also reporting problems with Medicare Advantage plans. An online survey of more than 2,200 AMA member physicians conducted in March found that patients had difficulty understanding how the plans work or have had coverage denials for services that were covered under traditional Medicare plans.

For example, about 84% of physicians with patients in Medicare Advantage managed care plans reported that their patients had difficulty understanding how the plan works, as did about 80% of physicians with patients in Medicare Advantage private fee-for-service plans.

—Mary Ellen Schneider