PhRMA, Senate Panel Reach A Consensus on Part D Trap

BY JOYCE FRIEDEN

Major pharmaceutical firms have agreed to offer drug discounts to Medicare beneficiaries trapped in the Part D "doughnut hole," President Obama announced.

The president endorsed an agreement between the Pharmaceutical Research and Manufacturers of America (PhRMA) and Sen. Max Baucus (D-Mont.), chairman of the Senate Finance Committee.

Mr. Obama explained that "as part of the health care reform I expect Congress to enact this year, Medicare beneficiaries whose spending falls within this gap will now receive a discount on prescription drugs of at least 50% from the negotiated price their plan pays. It's a reform that will make prescription drugs more affordable for millions of seniors, and restore a measure of fairness to Medicare Part D."

The estimated cost of the discount program, which applies only to brand-name drugs, is $80 billion over the next decade.

Medicare Part D enrollees who are in the doughnut hole will receive their discounts at the pharmacy and will not have to fill out any additional paperwork. They also will receive credit for the full cost of a drug against their spending obligation in the doughnut hole, even though they are actually paying half that amount.

President Obama noted that under the Medicare Part D prescription drug benefit, "Medicare covers up to $2,700 in yearly prescription costs and then stops, and the coverage starts back up when the costs exceed $6,100. [That] means between $2,700 and $6,100, folks are out of luck. And this gap in coverage has placed a crushing burden on many older Americans who live on fixed incomes and can't afford thousands of dollars in out-of-pocket expenses."

At the White House event, Barry Rand, CEO of AARP, which endorsed the agreement, called the deal "an early win for reform and a major step forward."

Mr. Rand said, "Too many Americans who fall into the coverage gap stop taking their medications because they simply cannot afford them. They will now have a new opportunity to lead a healthier life."

Billy Tauzin, president and CEO of PhRMA, noted in a statement that "even though we have had policy disagreements in the past [with AARP], this is an historic coming-together moment."

Sen. Baucus noted in a statement that when it was created, the Part D benefit "helped address the problem of skyrocketing prescription drug prices for millions of seniors. [With this agreement] we helped fill the gap in coverage and finished the job. … This benefit is part of our continued commitment to seniors and our ongoing effort to reform health care by lowering health care costs and ensuring all Americans have access to the quality, affordable health care coverage they deserve.

The Medicare Rights Center, a consumer group that advocates improved Medicare benefits, expressed cautious optimism about the agreement. "As always, the devil is in the details," center president Joe Baker said. "We look forward to working with President Obama and the Congress to making the promised discount most useful." ■

White House Releases Final Stem Cell Research Guidelines

BY JOYCE FRIEDEN

Federally funded human embryonic stem cell research may only use stem cells from embryos created by in vitro fertilization for reproductive purposes and that are no longer needed, according to final guidelines issued by the Obama administration.

The human embryonic stem cells (hESCs) must be donated by individuals "who gave voluntary written consent for the human embryos to be used for research purposes," according to the guidelines. Researchers must obtain written documentation that hESCs meet requirements, including:

- ▶ All options for disposition of embryos no longer needed for treatment were explained to the donors.
- ▶ No payments of any kind were offered for the embryos.
- ▶ Policies were in place ensuring that neither consenting nor refusing to donate embryos would affect the treatment given to any patient.
- ▶ Decisions about whether to donate embryos were made free of influence from stem cell researchers.
- ▶ Donors were informed that they retained the right to withdraw their donation up until the embryo was used.

"The guidelines will ensure that [National Institutes of Health]–funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law," according to a statement from the NIH, which will oversee all federally funded hESC research. "Internal NIH policies and procedures, consistent with [President Obama's March 9 executive order] and these guidelines, will govern the conduct of intramural NIH stem cell research."

Under the Bush administration, federal funding for human embryonic stem cell research was limited to studies using only the few stem cell lines that were in existence when the policy was created in August 2001.

President Obama's executive order lifted those restrictions and allowed funded research to include embryonic stem cell lines created after that date. It also called for the NIH to develop new stem cell research guidelines.

However, the order did not lift a current ban on using federal funds to create stem cell lines if the creation involved destruction of human embryos. Federal policy does not affect privately funded stem cell research.

One question raised by the executive order was how the guidelines would treat stem cell lines already in existence when the guidelines were issued.

In a document accompanying the guidelines, NIH officials note that "many lines were derived consistent with ethical standard and/or guidelines developed by various states, countries, and other entities such as ... the National Academy of Sciences. These various policies have many common features, rely on a consistent ethical base, and require an informed consent process, but they differ in details of implementation."

The guidelines authorize use of such stem cell lines if they are either compliant with the new guidelines or if they undergo a review by an NIH working group. "Working group review will enable pre-existing hESCs derived in a responsible manner to be eligible for use in NIH-funded research," the document states.

The draft hESC guidelines generated 49,000 comments. ■

Proposal Gets Mixed Reviews

Pay Plan *from page 1*

the same time, the agency would increase the work relative value units for new and established office visits, increase the work values for initial hospital and initial nursing facility visits, and incorporate the increased use of these visits into the practice expense and malpractice relative value unit calculations.

"We believe the rationale for a different payment for a consultation service is no longer supported because documentation requirements are now similar across all [evaluation and management] E&M services," the CMS wrote in the proposed rule.

The elimination of consultation codes will hurt academic dermatologists the most because they perform a lot of consults for patients with complex conditions, Dr. Coldiron said. "I think we ought to be supporting medical dermatology."

The proposed rule is considered good news for primary care. For example, the proposed rule includes plans to increase payments for E&M services and increased payment for the Welcome to Medicare physical, which focuses on primary care, health promotion, and disease prevention.

The CMS estimates that the combination of the various proposals would mean a 6%-8% payment increase for primary care physicians, excluding the impact of the 21.5% cut.

Another major part of the proposal is a plan to remove physician-administered drugs from the sustainable growth rate (SGR)—the statutory formula used to set physician payment rates under Medicare. Physicians' organizations have sought the repeal of the SGR for many years saying that it is flawed and does not reflect the true cost of providing medical care. A major criticism of the formula is that it counts the price of physician-administered drugs, over which physicians have little control, as a physician service.

Since the SGR is designed to cut payments when health care expenditures rise above a certain target, the inclusion of drugs has caused physicians to exceed those targets more rapidly and has contributed to pay cuts over the years.

The removal of physician-administered drugs from the SGR should reduce the number of years that physicians see pay cuts, according to the CMS. And the American Medical Association is betting that the change will make it less expensive for Congress to repeal the SGR, which would also benefit physicians.

Even if enacted, the proposal will not stop the 21.5% pay cut slated to go into effect on Jan. 1, 2010. However, several physicians interviewed said they were hopeful that Congress would step in again this year to roll back this cut, whether through health reform legislation or in a separate bill.

The fee schedule proposal also includes policy changes related to imaging. The proposed rule would cut payments for certain high-cost imaging services by assuming that imaging equipment priced at more than $1 million is used 90% of the time, compared with the current assumption of use at 50%.

Overall, the proposed fee schedule is not good for dermatologists or any specialist.

DR. COLDIRON

The proposed change is based on studies from the Medicare Payment Advisory Commission (MedPAC) showing that the use of high-cost imaging equipment is higher than previously thought.

For example, MedPAC found that in certain markets, MRIs were being used an average of about 46 hours a week, or 92% of a 50-hour workweek.

The agency said it will continue to examine the data for equipment valued at less than $1 million but is not proposing a change at this time. ■