American Latex Allergy Association

Medicare cuts payments for pharmacy-made drugs

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?Significantly lower? scale to remove any profit incentive
By Julie Appleby
USA TODAY

WASHINGTON ? In a sweeping change, Medicare says it will significantly cut payments to pharmacies that make their own, non-FDA-approved versions of drugs used by asthmatics and others with respiratory ills. The move was disclosed in a letter sent Tuesday to Sen. Charles Grassley, R-Iowa. He and some consumer advocates say patients may unknowingly get such drugs, which have provided profits for pharmacies, but are made under less-stringent safety and sterility rules than the government sets for drug manufacturers. It follows action earlier this month by the Food and Drug Administration, which warned three large national medical-supply companies that their pharmacies may be violating federal law by mass producing ?thousands of doses? of unapproved respiratory drugs. Starting in January, Medicare will use special payment codes for pharmacy-made respiratory drugs, allowing it to pay less for those products than for brand-name formulations. For most drugs, Medicare has until now paid the same, no matter whether the pharmacy bought the drugs from manufacturers, or purchased raw ingredients and made them in-house. The new payments are likely to be ?significantly lower? and will remove ?any inappropriately large financial incentives? encouraging pharmacies to make drugs for patients, even when there is no medical reason to switch from products made by drug manufacturers, Medicare chief Mark McClellan said in a letter to Grassley. At issue are liquid drugs used to treat lung conditions. The drugs are inhaled using a tabletop device called a nebulizer. The FDA says patients are unlikely to get such drugs from national chain pharmacies. Instead, most get them from Internet mail-order pharmacies or firms that sell the devices used to inhale the drugs. Pharmacists are allowed to make drugs when they have specific prescriptions for patients who need specialized treatments that are not available from brand-name manufacturers. Pharmacy-made drugs are not generic drugs, which are produced by commercial manufacturers. Both brand and generic drugs must receive FDA approval. Pharmacy-made drugs do not. Medicare says it is not trying to stop legitimate pharmacy-made drugs. In July, Grassley wrote Medicare and the FDA, saying former industry employees told his staff that some pharmacies switch patients to pharmacy-made drugs without telling them or their doctors. Tests conducted by pharmaceutical companies on samples of pharmacy-made drugs found contamination and incorrect dosage amounts, Grassley?s letter added. Grassley on Wednesday called McClellan?s reply a ?very positive response.? Medicare now has a separate payment code for only one pharmacy-made version of the 37 respiratory drugs it covers. That code, for a drug called budesonide, cut payment from $4.40 a dose to 29 cents, according to a recent Securities and Exchange Commission filing by pharmacy Rotech Healthcare, one of the three firms recently warned by the FDA. Rotech said the change could cut its revenue $30 million this year.

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American Latex Allergy Association

P.O. Box 198

Slinger, WI 53086

Phone: 262-677-9707 1-888-97-ALERT

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