SPECIALTY PHARMACY NEWS

NHIA: Change in Competitive Bid Program Could Jeopardize Care

CMS's decision to add infusion pumps to the Medicare Durable Medical Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS) Competitive Bidding Program could have a dire impact on patient care and health care costs, among other things, says the National Home Infusion Association (NHIA). With that in mind, the association is requesting clarification on multiple issues.

While the pumps were not included in the first round of the program, which covered nine Competitive Bidding Areas, or the second round, which adds 91 CBAs, CMS chose to add them during the Round 1 Recompete, which began Jan. 1. Drugs administered through the pumps are not included in the Recompete, which will result in a "bifurcated benefit," through which a DME provider would provide the pump and an infusion pharmacy would provide the drug, contends the association in a recent letter.

Although it is possible that both products could be supplied by the same firm, NHIA says that "nearly half the companies awarded contracts in the External Infusion Pumps and Supplies category do not have pharmacies capable of preparing and dispensing infused drugs." The association says the "bid determination process is likely to award contracts to general DME suppliers, strictly based on price, with no guarantee that they will be able to work closely with licensed pharmacists." Because of patient safety, liability and regulatory concerns, "many home infusion pharmacies are reluctant to dispense drugs if they do not control the pumps and supplies" used to administer the therapies.

The letter maintains that "there are limitations as to what can and cannot be subcontracted." According to Russell Bodoff, president and CEO of NHIA, "Because the drug and the pump would be coming from separate suppliers, subcontracting creates problems with liability and control of the delivery of both the pump and drugs. Only a pharmacy can bill the Medicare program for drugs, and only a winning DME supplier can bill for the infusion pump. Thus, one cannot subcontract with the other. They have to bill Medicare separately," he explains to *SPN*.

"This has the very real potential" to push patients away from the cost-effective home infusion setting to higher-cost infusion sites such as hospitals or skilled nursing facilities, says the group.

CMS did not respond to *SPN*'s requests for comment.

Asked about why CMS may be including infusion pumps in the Recompete when it did not include them in Round 2, Bodoff notes that the Recompete is only nine CBAs compared with an additional 91 in Round 2. "We believe that CMS is testing this policy before considering a larger scale inclusion of infusion pumps in competitive bidding, which suggests to us that CMS also has some concerns as to how the application of competitive bidding to external infusion pumps will work."

NHIA Asked FDA to Intervene

NHIA says it "has submitted its concerns about this issue to CMS on several occasions. Unfortunately, CMS has yet to address those concerns," says the group in an attachment to a Dec. 5 letter to FDA Commissioner Margaret Hamburg, M.D. For that reason, the group reached out to the FDA in the hope that it would intervene with respect to specific questions that NHIA has. The letter cites sections of the FDA's 2010 Infusion Pumps Improvement Initiative, including that pharmacists confirm that settings on a pump are correct before giving it to a patient or clinician, and that pharmacists work with a multidisciplinary team to monitor any pump incidents. For these reasons, including infusion pumps in the DMEPOS Competitive Bidding Program "is unintentionally and alarmingly short-sighted, as it introduces serious risk to patients and is utterly contrary to the FDA's own recommendations" as outlined in documents provided through the 2010 initiative.

"This letter to the FDA outlines the direct inconsistencies between the actions of the FDA and CMS, and requests FDA's intervention," says Bodoff.

"If CMS cannot provide detailed answers to these questions we believe the FDA should request a delay or halt to the inclusion of infusion pumps" in the current and future rounds of the program, says the letter.

When *SPN* contacted the FDA for comment, subject matter experts at the agency declined to comment and said they "defer to CMS officials" on the issue.

Specifically, NHIA is requesting feedback on the following seven questions:

(1) Will the DME supplier or the infusion pharmacy determine the method of administration — an ambulatory or stationary pump?

(2) Will the DME supplier or the infusion pharmacy provide patient training in how to use the equipment and supplies?

(3) Will the DME supplier or the infusion pharmacy program the pump?

(4) Will the DME supplier or the infusion pharmacy handle after-hours patient calls?

(5) When a replacement pump is needed, will the DME supplier or the infusion pharmacy program and deliver it?

(6) Will the DME supplier or the infusion pharmacy be responsible for changing a pump program and delivering the pump when a patient's medication order changes?

(7) "Who will be responsible for repairs and loaner equipment when maintenance and servicing are required for external infusion pumps that have already capped prior to implementation of" competitive bidding?

Because NHIA did not receive clarification by the time the program started, "We are urging our members to work in good faith to ensure patients are treated appropriately as these questions are answered," Bodoff tells *SPN*. "While we have concerns with the program, ensuring our patients get the care they require is of utmost importance.…Our No. 1 concern is that patient safety is at risk, and needlessly so. Infusion is a lifesaving often daily service that needs to be well coordinated. If a patient cannot obtain his or her medication, or if the medication does not match the pump, there could be catastrophic consequences."

Read the NHIA letter at http://tinyurl.com/lmpd6dg. Contact Bodoff at russell.bodoff@nhia.org. ✧