



Lincare Holdings Inc. Comments on Proposed Medicare Payment Rule for Respiratory Therapy Drugs

CLEARWATER, Fla., Jul 29, 2004 /PRNewswire-FirstCall via COMTEX/ -- Lincare Holdings Inc. (Nasdaq: LNCR), a leading provider of respiratory therapy services to patients in the home, today issued a statement on a proposed rule, CMS-1429-P (the "proposed rule"), published yesterday by the Centers for Medicare and Medicaid Services ("CMS"). The proposed rule, among other things, addresses certain provisions contained in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 (the "Medicare bill") affecting Medicare reimbursement for respiratory therapy drugs used in conjunction with nebulizers by patients suffering from chronic obstructive pulmonary disease ("COPD").

CMS acknowledges in the rule that Medicare beneficiaries may soon be denied access to life enhancing respiratory therapy drugs and that a higher dispensing fee to compensate pharmacies for the cost of providing respiratory therapy drugs should be seriously considered. In the absence of a reasonable dispensing fee to cover the necessary costs incurred in providing these nebulizer medications in the home setting to COPD patients as prescribed by their physicians, Lincare plans to cease providing respiratory therapy drugs and will send appropriate notices to its patients by mid-October so that they can make alternative treatment arrangements, no matter how inadequate.

The proposed rule also posits metered dose inhalers ("MDIs") as a viable treatment alternative in the event that access to nebulizer drugs is disrupted, but MDIs represent a non-covered and potentially inappropriate medication delivery system for this patient population that would cause these Medicare beneficiaries to experience a deterioration in the quality of their care and to incur significantly higher out-of-pocket costs next year.

The proposed rule would implement provisions of the Medicare bill which would dramatically reduce Medicare payment amounts for respiratory therapy drugs, such as albuterol sulfate and ipratropium bromide, provided by pharmacies such as Lincare to COPD patients. Consistent with the provisions of the Medicare bill, the proposed rule would reform the current reimbursement methodology from 80% of average wholesale price ("AWP") to average sales price ("ASP") plus 6% beginning in 2005. CMS has provided a preliminary estimate of 2005 reimbursement amounts for respiratory therapy drugs under the ASP formula that are approximately 89% below the current payment amounts for these medications.

CMS states in the proposed rule its concern that, given the overall reduction in payment rates for respiratory therapy drugs, access to these drugs by Medicare beneficiaries suffering from COPD and other lung diseases could be significantly disrupted. CMS proposes to establish a separate dispensing fee that will be paid in addition to the payment amount for the drug. CMS is seeking comments that would assist the agency in setting an appropriate dispensing fee that reflects the costs of the shipping, handling, compounding and other pharmacy activities, including direct labor and non-labor costs, as well as indirect costs of overhead, required to furnish respiratory therapy drugs to Medicare beneficiaries.

Lincare does not believe that the ASP payment amounts for the drugs alone, in the absence of a meaningful increase in the dispensing fee, would adequately compensate pharmacies for respiratory therapy drugs and, if implemented as such, the regulation will eliminate access to these critical respiratory medications by more than one million COPD patients across the United States. In the absence of an adequate dispensing fee, the regulation will severely limit the availability of an effective and clinically established treatment regimen for chronic lung disease.

CMS offers as an alternative the option of forcing patients to regress to the use of MDIs. The vast majority of critically ill COPD patients currently using nebulizers either have unsuccessfully attempted to use MDIs in the past or have had their treating physician consider the initial or continued use of MDI's and determined it to be inadequate for the health needs of the patient. Lincare believes that reliance on MDIs will cause an enormous shift in the economic and physical costs and burdens of treatment of COPD to the patient and to other health care resources.

John P. Byrnes, Lincare's Chief Executive Officer, said, "Lincare is evaluating the impact of the proposed rule on reimbursement rates for respiratory therapy drugs and will closely monitor the development of the final regulation. We are concerned that CMS does not yet fully understand the severity of the potentially harmful impact of the proposed regulation on the large number of Medicare beneficiaries suffering from chronic lung disease. We are extraordinarily concerned that the outcome of the proposed rule would be a substantial increase in out-of-pocket costs to Medicare beneficiaries for non-covered drug and acute care therapies and diminishment in quality of care for COPD patients. We remain confident that inadequate reimbursement levels or severe access limitations to needed respiratory care is not the intent of Congress. We strongly urge CMS to substantively and expeditiously alter the proposed regulation to ensure that insufficient payment rates do not unnecessarily put the health of some of our nation's most vulnerable seniors at severe risk."

Mr. Byrnes added, "We are hopeful that Medicare payment levels will allow us to continue to provide respiratory therapy drugs to Medicare beneficiaries suffering from COPD. The respiratory products and services provided by Lincare to these critically ill patients in the home setting are important and cost-effective components of the management of chronic lung disease."

COPD affects approximately 16 million people and is the fourth leading cause of death in the United States, following heart disease, cancer and stroke. Furthermore, it is the only major chronic disease currently increasing in prevalence and mortality. Comments on the proposed rule will be accepted by CMS until September 24, 2004. CMS plans to publish the final rule by November 1, 2004, with an effective date of January 1, 2005.

Lincare, headquartered in Clearwater, Florida, is one of the nation's largest providers of respiratory therapy services to patients in the home. The Company provides services and equipment to over 510,000 customers in 47 states.

Statements in this release concerning future results, performance or expectations are forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. All forward-looking statements included in this document are based upon information available to Lincare as of the date hereof and Lincare assumes no obligation to update any such forward-looking statements. These statements involve known and unknown risks, uncertainties and other factors that may cause Lincare's actual results, levels of activity, performance or achievements to be materially different from any results, levels of activity, performance or achievements expressed or implied by any forward-looking statements. In some cases, forward-looking statements that involve risks and uncertainties contain terminology such as "may," "will," "should," "could," "expects," "intends," "plans," "anticipates," "believes," "estimates," "predicts," "potential," or "continue" or variations of these terms or other comparable terminology.

Key factors that have an impact on Lincare's ability to attain any estimates contained in this release include potential reductions in reimbursement rates by government and third party payors, changes in reimbursement policies, the demand for Lincare's products and services, the availability of appropriate acquisition candidates and Lincare's ability to successfully complete and integrate acquisitions, efficient operations of Lincare's existing and future operating facilities, regulation and/or regulatory action affecting Lincare or its business, economic and competitive conditions, access to borrowed and/or equity capital on favorable terms and other risks described in the filings of Lincare with the Securities and Exchange Commission, including its annual report on Form 10-K for the year ended December 31, 2003.

In developing its forward-looking statements, Lincare has made certain assumptions relating to reimbursement rates and policies, internal growth and acquisitions and the outcome of various legal and regulatory proceedings. If the assumptions used by Lincare differ materially from what actually occurs, then actual results could vary significantly from the performance projected in the forward-looking statements. Lincare is under no duty to update any of the forward-looking statements after the date of this release.

SOURCE Lincare Holdings Inc.

Paul G. Gabos, Lincare Holdings Inc., +1-727-530-7700

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