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April 7, 2011

Nirav R. Shah, M.D., M.P.H.
Commissioner
NYS Department of Health
Corning Tower Building
Empire State Plaza
Albany, New York 12237

Re: Report 2010-F-46

Dear Dr. Shah:

Pursuant to the State Comptroller's authority as set forth in Article V, Section 1 of the State Constitution; and Article II, Section 8 of the State Finance Law, we have followed up on the actions taken by officials of the Department of Health to implement the recommendations contained in our audit report, *Medicaid Reimbursement of Synagis* (Report 2008-S-153).

Background, Scope and Objective

The New York State Medicaid program (Medicaid) provides medical services, including pharmacy services, to low-income individuals who meet program eligibility requirements. The Department of Health (Department) must provide eligible individuals with adequate access to prescription drugs in a cost efficient manner. Synagis, a prescription medication covered by Medicaid, helps to decrease the incidence of human respiratory syncytial virus (RSV) in infants that were born prematurely, or diagnosed with serious respiratory conditions like congenital heart disease or chronic lung disease. In the United States, RSV infections regularly peak in the winter months and often can lead to lower respiratory tract infections and, in more severe cases, pneumonia, in infants. RSV occurs in New York primarily between November and April, and is one of the leading causes of hospitalization for children under one year old. The Center for Disease Control establishes the RSV season by monitoring infection rates by region and can extend the season based on the percentage of cases of RSV that are confirmed in a population in the region.

Synagis typically is given in monthly injections throughout the RSV season at a dosage of fifteen milligrams for every kilogram of bodyweight. Synagis is an expensive drug, costing approximately \$2,000 a month for each individual. Medicaid paid approximately \$146 million in claims for Synagis during the period July 1, 2008 through February 25, 2011. The Department has issued guidelines for the prescription and use of Synagis in the Medicaid program. These guidelines closely reflect the guidance provided by other states and the manufacturer. In addition to these

guidelines, the Department has established guidelines for pharmacies to follow when filling Synagis prescriptions.

Our initial audit report, which was issued on October 15, 2009, examined whether the Department ensured that claims for Synagis were paid according to Department guidelines and controls. We found that the Department has not established edits in the eMedNY system to detect for further review payments that do not comply with Department guidelines. During the period July 1, 2005 to June 30, 2008, we identified approximately \$29.7 million of Medicaid paid claims for Synagis that did not meet Department guidelines. The objective of our follow-up was to assess the extent of implementation, as of March 11, 2011, of the three recommendations included in our initial report.

Summary Conclusions and Status of Audit Recommendations

Department officials have made progress in correcting the problems we identified in the initial report. Of the three prior audit recommendations, all three have been implemented.

Follow-up Observations

Recommendation 1

Take steps to ensure compliance with Department issued guidelines relating to duration of the RSV season, age of the individual receiving Synagis, and the number of doses an individual receives.

Status - Implemented

Agency Action - On September 23, 2010, the Department activated a modified prior approval edit on the eMedNY system to test whether a Synagis recipient is under two years old at beginning of the RSV season. The Department also modified this edit to test whether a claim is made outside of the RSV season as defined by the Center for Disease Control and Prevention (CDC). The edit can be altered to accommodate any change to the RSV season as announced by the CDC. Under this edit, claims submitted where the recipient does not meet the age or season requirements are denied. These modifications were first active for the 2010-2011 season that runs from October 16, 2010 through March 31, 2011.

Recommendation 2

Monitor the early refill edit to ensure it is working as intended and that it is not being excessively overridden.

Status - Implemented

Agency Action - Department officials periodically query the eMedNY data warehouse for a list of those Synagis pharmacy claims that include codes to override the edit limiting refills to a 21-day frequency. In the 2008-2009 RSV season, the list showed four such claims. Two of the override codes were for lost doses of Synagis; the other two were for doses refilled early for vacations. In the 2009-2010 RSV season, only one early refill claim overrode the edit, to

replace a lost dose of Synagis. Department officials stated that the decrease in overrides may be explained, in part, because pharmacists now need a physician's prior approval before using a code to indicate a vacation refill. Department officials first reviewed early refill lists in October and November 2009. Because so few overrides now occur, they have now turned to quarterly monitoring of override lists.

Recommendation 3

Continue to use the newly developed prescriber education program to communicate with prescribers regarding Synagis guidelines and controls.

Status - Implemented

Agency Action - During our initial audit, Department officials started a provider education program that would, among other things, address the use of Synagis. At that time the program's website provided only clinical information about Synagis; it did not address Medicaid guidelines and controls for this drug. Currently, Synagis information provided on the website addresses dosage limits and the age of recipient at the beginning of the RSV season. In addition, Department officials cited other communications where Synagis information was provided to prescribers. For example, in the September 2010 Medicaid Update, the Department advised of the need for prior approvals for recipients outside of the Synagis age range or the RSV season and drug dose limitations.

Major contributors to this report were Karen Bogucki and Donald Collins.

We thank the management and staff of the Department of Health for the courtesies and cooperation extended to our auditors during this process.

Very truly yours,

Edward J. Durocher, CIA
Audit Manager

cc: Mr. Thomas Lukacs, Division of the Budget
Mr. Stephen Abbott Department of Health
Mr. Stephen LaCasse Department of Health