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August 19, 2010

The Honorable Kathleen Sebelius
Secretary of Health and Human Services
200 Independence Avenue, S.W.
Washington, DC 20201

Dear Secretary Sebelius,

As an organization that promotes safe and effective medication use in children, the Pediatric Pharmacy Advocacy Group (PPAG) strongly believes that Section 2302 of the Health Care and Education Reconciliation Act (HCERA), which was added to the Public Health Service Act by the Patient Protection and Affordable Care Act, should not apply to children's hospitals. Section 2302 exempts orphan drugs from required discounts for 340B entities, including free-standing children's hospitals and will result in significant financial losses. As Congress works on a technical legislative correction, we would appreciate your support to ensure that children's hospitals do not lose this critical benefit.

As you know, children's hospitals were originally added to the list of covered entities through Section 6004 of the Deficit Reduction Act (DRA) of 2005. Though the DRA was signed into law in 2006, the final guidelines were not released until September 2009. There are currently 19 children's hospitals participating in the 340B program.

Free-standing children's hospitals were purchasing orphan drugs through the 340B program before HCERA was signed into law. These hospitals use a number of the three-hundred forty-seven (347) drugs daily that have received orphan drug status. It is predicted that buying orphan drugs at full price will increase the costs of these drugs to children's hospitals by 50 to 100 percent. If this provision is applied to children's hospitals, they will be forced to leave the 340B program because this provision could actually increase overall drug costs to children's hospitals.

The appropriate members of Congress have been alerted to this issue and are working on the correction. While Congress works on the correction, we respectfully request that you delay implementation of this provision to prevent children's hospitals from losing this important benefit. Moreover, the Health Resources and Services Administration should use the full rule-making process to provide clarity to a number of complex questions raised by the orphan drug provision.

Thank you for your consideration. For additional information, please contact us at PPAG at 1-888-316-3617.

Sincerely,

Michael Christensen
President and Chair of the Board of Directors

cc: Mary Wakefield, Ph.D., R.N., Administrator, Health Resources and Service Administration
Jimmy Mitchell, R.Ph., MPH, MS, Director of the Office of Pharmacy Affairs