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CIS To Hold Special Government Programs Forum Call on CMS' Proposed Rule

PHILADELPHIA, Pa., Jan. 30, 2012 – Compliance Implementation Services (CIS), a leading life sciences consulting firm, announced today that it will host a complimentary teleconference to provide a more detailed overview of the Proposed Rule which was released by the Centers for Medicare & Medicaid Services (CMS) on Friday, January 27. Joseph Metro of Reed Smith LLP will join the call as a guest speaker. This rule will revise requirements of Medicaid reimbursement programs for covered outpatient drugs and other areas of Medicaid coverage, payment and rebates, including:

- Reimbursement to pharmacy for ingredient costs
- AMP for Authorized Generics
- Inclusion of territories in Medicaid Rebate Program

The teleconference will be held on Thursday, February 2nd from 2:00-3:00pm EST for insight on the new AMP Rule. CIS and Reed Smith will be providing a high-level review of the Proposed Rule and offering initial reaction to the news. Participants may join the call by dialing 888-206-2266 at that time. When prompted for a participant code, enter 9449409. Questions regarding the AMP Rule may be submitted in advance to info@cis-partners.com.

“As we have been awaiting the Final Rule, the key thing we have been wondering is whether CMS would propose a “build up” methodology, making a major shift from the long standing approach of the “Gross to Net” methodology,” said Chris Cobourn, Vice President of Regulatory Compliance. “It is important to read into this topic, as CMS discusses its views on both approaches, but suggests that they are leaning to the buildup approach. I think it is very important that manufacturers do provide comments on this approach, as we all know that this would be very difficult to do with our existing data sources and systems, and it would be a completely different approach of our other calculations.”

The purpose of the Proposed Rule is to establish AMP regulations to define and implement changes to Medicaid Average Manufacturer Price (AMP) under the Patient Protection and Affordable Care Act (PPACA).

A Proposed Rule allows for a comment period, with a Final Rule to be published at a later date. As a guide to general timelines, in December 2006, the AMP Proposed Rule was published, with the Final Rule published in July and effective Q4 of 2007. This AMP Final Rule was withdrawn in November 2010, as it was in conflict with legislative mandates in the PPACA.

Comments on the Proposed AMP Rule are due by April 2, 2012.

About Compliance Implementation Services (CIS)

Compliance Implementation Services (CIS) is a life sciences consulting firm specializing in compliance strategies for pharmaceutical, biotech, and medical device companies, from global clinical research and development, through manufacturing, commercial compliance, and government programs. CIS provides its clients with a deep understanding of industry laws and regulations, innovative and practical applications, and custom solutions to establish a “Culture of Compliance” that is both meaningful and sustainable.

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