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August 16, 2012

Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1589-P; Jennifer Bean
P.O. Box 8013
Baltimore, MD 21244-1850

Dear Jennifer Bean,

In review of the CMS SDPS Memorandum number 12-257-OD dated August 13, 2012, I am highly concerned to learn the outpatient quality measure OP-16 has been removed from the calendar year 2013 hospital outpatient quality reporting program.

Cited by CMS were patient concerns due to the Class I recall. Although it was also cited not to be a platform decision, industry is fully aware of the recent major recalls and logistical struggles of Alere. The original decision by CMS to enact OP-16 was, in the view of many, a tremendous step forward by CMS to demand better quality from its caregivers in the United States. Likewise, it was refreshing to see the initiatives of the quality mandated by CMS to be in-line with the TAT requirements of our industry's leading organizations in cardiology and laboratory medicine. Removing OP-16 based on the deficiencies of one platform, is counter-productive to the quality initiatives of the ACA and improving patient outcomes.

There are new and improved troponin testing technologies available today at the point of care from various manufacturers that can help hospitals improve TAT and meet the requirements of OP-16, safely. Better technologies that are also capable of delivering sensitivities that are far superior to immunochromatic platforms and comply with the Universal Definition of AMI. By removing OP-16, regardless of a 60-minute troponin TAT recommendation of CMS, CMS has stifled the motivation of hospital executives to quickly improve their hospital's capabilities in this regard.

I strongly request CMS reenacts OP-16 but with a temporary suspension of the reimbursement penalty. With a reenactment, as originally intended OP-16 will improve quality and in doing so save money and thousands of lives.

Sincerely,

A handwritten signature in black ink, appearing to read "John Hadesky", written in a cursive style.

John Hadesky
Chief Operating Officer