Clinical Laboratory Provisions In H.R. 6331

- **Clinical laboratory tests (Sec. 145)** – Repeals the competitive bidding demonstration project for clinical laboratory services. Reduces the payment update for clinical laboratory services by 0.5% in each of the next 5 years. According to a proposed rule published by CMS (CMS-1403-P) for 2009, the Part B clinical laboratory fee schedule will be updated by the percentage increase in the Consumer Price Index for All Urban Consumers (CPI-U) using the 12-month period ending with June of the previous year.

  The preliminary CPI-U for the 12 months ending June 30, 2008, is 5.0%. Although this figure may be slightly adjusted up or down, whatever the final number is will be reduced by 0.5% to produce the final CPI increase effective January 1, 2009.

- **Extension of treatment of certain physician pathology services (Sec. 136)** – Extends for 18 months the provision that allows independent laboratories providing services to hospitals that utilized independent laboratories prior to the November 1999 final physician fee schedule rule to continue to bill Medicare directly for the physician pathology services they provide to hospitals.

- **Pathology services billed under the Medicare Physician Fee Schedule** – For pathology services billed under the Medicare physician fee schedule (MPFS) rather than the clinical laboratory fee schedule (CLFS), payments will increase 1.1% effective July 1, 2008, avoiding a scheduled 10.6% reduction.

- **Improvements to coverage of preventive services (Sec. 101)** – Authorizes the Secretary to cover new preventive services under the Medicare national coverage determination process that are recommended by a new U.S. Preventive Services Task Force. While new preventive services would be subject to a copayment, any clinical laboratory tests included as new preventive services would not, as they would be paid pursuant to the Clinical Laboratory Fee Schedule (CLFS).

- **Clarification of payment for clinical laboratory tests furnished by critical access hospitals (Sec. 148)** – Allows Critical Access Hospitals (CAHs) serving rural areas to receive 101% of reasonable costs for clinical laboratory services provided to Medicare beneficiaries regardless of whether the laboratory specimen was collected in the hospital or off-site at another facility operated by the Critical Access Hospital.

- **Renal dialysis provisions (Sec. 153)** – Provides a 1.0% update to the composite rate for renal dialysis services for each of 2009 and 2010. Creates a site-neutral composite rate for dialysis services.

  Requires the Secretary to establish, by January 1, 2011, a fully bundled payment system for the treatment of end-stage renal disease (ESRD) and establishes a permanent market-based update to providers of renal dialysis services. Specifies the scope of items and services to be included in the bundled payment, including drugs, biologs and laboratory tests that are currently paid for separately. Requires use of case mix adjustors to payments as well as add-ons for low-volume providers. Allows adjustments based on a geographic index and for pediatric and rural providers. Establishes a four-year phase-in of the new system.

  Establishes a quality incentive payment program for ESRD providers, effective January 1, 2011. Requires providers of ESRD services to meet quality metrics endorsed by a consensus-based, standard-setting body by demonstrating improvement or high levels of achievement.