



American
Clinical Laboratory
Association

December 16, 2009

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Ms. Charlene Frizzera
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G
Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, D.C. 20201

RE: CMS-1418-P: Medicare Program: End-Stage Renal Disease Prospective Payment System: Proposed Rule

Dear Ms. Frizzera:

The American Clinical Laboratory Association (ACLA) is pleased to have this opportunity to submit comments with regard to the Medicare Program: End-Stage Renal Disease Prospective Payment System: Proposed Rule (the "Proposed Rule.") ACLA is an organization representing clinical laboratories throughout the country, including local, regional, and national laboratories, including dialysis specialty laboratories. Because the Proposed Rule includes provisions of significance to clinical laboratories, it could have a direct impact on laboratories.

ACLA's principal concern relates to the Proposed Rule's inclusion of separately billable laboratory tests in the proposed End-Stage Renal Disease Prospective Payment System (ESRD PPS) and how it proposes to define which laboratory tests are included in the bundled payment. The statute requires that diagnostic laboratory tests not included under the composite payment rate and that are "furnished to individuals for the treatment of [ESRD]" must be included as part of the ESRD prospective payment bundle. The Centers for Medicare and Medicaid Services (CMS) proposes to define such laboratory tests as tests that are separately billed by ESRD facilities as of December 31, 2010 as well as laboratory tests ordered by a physician who receives monthly capitation payments (MCPs) for treating ESRD payments and billed by independent laboratories.

ACLA supports including in the proposed bundle of services laboratory tests separately billed by ESRD facilities; however, we do not support the inclusion of all laboratory tests ordered by the MCPs. Including all tests ordered by MCPs would capture a universe of tests that are wholly unrelated to the treatment of ESRD. ESRD patients often have multiple medical conditions unrelated to their ESRD, and the MCP physicians order tests to diagnose and treat those conditions because they are also serving as the primary care providers for these patients. Independent laboratories, which would otherwise be willing to contract with dialysis facilities because the burdensome billing requirements of the old program have been eliminated, will be discouraged from doing so because of the uncertainty of adequate payment.

1100 New York Avenue, N.W. * Suite 725 West * Washington, DC 20005 * (202) 637-9466 Fax: (202) 637-2050

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As such, ACLA strongly urges CMS to develop a list of those laboratory tests related directly to the treatment of ESRD, which would ensure that the costs of providing those services are captured completely and accurately in the bundled payment and those services not directly related to the treatment of ESRD would continue to be paid separately to the independent laboratory. Specifically, ACLA supports the Kidney Care Council's (KCC's) proposed list of approximately 50 laboratory tests representing approximately 95 percent of all tests ordered by dialysis facilities and approximately 95 percent of total laboratory revenue. The approximately five percent of laboratory tests ordered by MCPs for ESRD beneficiaries that are not directly related to the treatment of ESRD would include, among others, prostatic specific antigen (PSA), oncology tests, thyroid tests, drug screens and therapeutic drug levels for certain medications. As recommended by the KCC, for these laboratory tests that are unrelated to the treatment of ESRD CMS should clearly instruct dialysis facilities and independent laboratories that such tests will continue to be billed directly by the laboratory to the Medicare program when ordered by either the MCP or another physician regardless of where the specimen is drawn.

ACLA appreciates your consideration of our comments, concerns, and suggestions regarding the Proposed Rule. If you have any questions or would like to discuss any of the issues we discuss here further, please do not hesitate to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read 'JoAnne Glisson', with a stylized flourish at the end.

JoAnne Glisson
Senior Vice President