



ACLA Comment

“Expanding Health Care Coverage: Proposals to Provide Affordable Coverage to All Americans”

Report Released from Senate Finance Committee May 14, 2009

The American Clinical Laboratory Association (ACLA) applauds the Senate Finance Committee for recognizing the importance of prevention and wellness and providing options to improve access to preventive services and encourage healthy lifestyles. The report is generally consistent with two necessary overarching principles noted below. For the full benefit of prevention and wellness, more specific comment with suggested word changes underlined and highlighted are also provided.

Preventive and early diagnostic lab services are an integral component of true health reform and should be a covered benefit in all health plans. A reformed health care system must make screening, wellness and prevention of equal importance to treating disease. The result would be more complete health care, healthier Americans and significant cost savings to the system.

Laboratory services must be part of covered benefits in all health plans and not be access diminished by a co-pay or deductible hurdle. Laboratory medicine stands at the front line in addressing today’s most urgent health care challenge—providing better, more-effective care, while reining-in rising health care costs. Information from laboratory tests enables early detection and targeted therapy that, together, are changing the course of the most costly and damaging diseases—cancer, heart disease, chronic kidney disease, HIV, and diabetes, among others. Clinical laboratory services comprise less than 5% of hospital costs and about 1.6% of all Medicare costs, but influence 60-70% of health care decisions and offer a high value proposition for the health care system as a whole.

ACLA appreciates the opportunity to provide the following specific comments to the Senate Finance Committee and pledges our commitment to help shape and improve the future of health care in our nation.

SECTION II: Making Coverage Affordable

Benefit Options

Proposed Options (Page 9)

All health insurance plans in the non-group and small group market would be required, at a minimum, to provide a broad range of medical benefits, including but not limited to, preventive and primary care, emergency services, hospitalization, physician services, outpatient services, day surgery and related anesthesia, **clinical laboratory diagnostic testing and screening**, diagnostic imaging and screenings, including x-rays, maternity and newborn care, medical/surgical care, prescription drugs, radiation and

chemotherapy, and mental health and substance abuse services, which at least meet minimum standards set by federal and state laws. In addition, plans could not include lifetime limits on coverage or annual limits on any benefits and cannot charge cost-sharing (e.g., deductibles, co-payments) for preventive care services. Another option would be to allow plans to charge nominal cost-sharing for prevention services **other than for clinical diagnostic testing and screening.**

*ACLA Comment: The proposed wording changes are necessary to insure that laboratory testing services are part of covered benefits in all health plans and not access diminished by a co-pay or deductible hurdle. **It is extremely important that the changes proposed for expanding the charge of and evidence criteria used by the US Preventive Services Task Force in Section VI of the report (below) be included and integrated in the benefit options for the health insurance plans in the non-group and small market discussed above.** There is a need to establish a similar approach to develop screening laboratory test recommendations that include periodicity and interval testing from birth to Medicare, similar to what has been developed by the American Academy of Pediatrics “Bright Futures” approach to address children’s medical screening needs.*

SECTION VI: Options to Improve Access to Preventive Services and Encourage Health Lifestyles: Prevention and Wellness

Promotion of Prevention and Wellness in Medicare

Personalized Prevention Plan and Routine Wellness Visit

Proposed Option (Page 44)

Within six months of completing the comprehensive health risk assessment (HRA), the option would authorize Medicare payment for a visit to a qualified health professional to create a personalized prevention plan. The plan would include the following elements: review and update medical and family history; measure the patient’s blood pressure, body mass index and any other measurements identified above not included the HRA; **conduct appropriate clinical laboratory testing,** provide a schedule and referral for recommended, appropriate, covered preventive services and immunizations; provide a strategy to address identified conditions and risk factors; identify all medications currently prescribed and all providers regularly involved in the patient’s care; and offer health advice and referral to Medicare-covered health education and preventive counseling or referral to community based interventions to address modifiable risk factors such as weight, physical activity, smoking, and nutrition. Optional elements, if appropriate, include referrals for **additional** diagnostic testing, or referrals to review treatment options for beneficiaries with chronic conditions; end of life care planning, and administration of appropriate Medicare covered immunizations and screening tests. No co-payment or deductible applies.

ACLA Comment – The full benefit of a “comprehensive health risk assessment” and a “personalized prevention plan” will not be achieved without the inclusion of a panel of laboratory tests that will identify chronic disease. The opportunity to modify risk and reduce or eliminate costly adverse complications from disease is dependent upon appropriate clinical laboratory testing.

Incentives to Utilize Preventive Services and Engage in Healthy Behaviors

Proposed Option (Page 45)

This option would remove or limit beneficiary cost-sharing (co-payment, deductible or both) for preventive services covered under Medicare and rated “A” or “B” by the U.S. Preventive Services

Task Force (USPSTF) or recommended by the Advisory Committee on Immunization Practices, National Institutes of Health, Centers for Disease Control and Prevention, Institute of Medicine, specialty medical associations, patient groups, scientific societies, or the Clinical Laboratory Improvement Advisory Committee (CLIAC) . The option would also encourage the Secretary to establish a mechanism to provide refunds or other incentives to Medicare beneficiaries who successfully complete certain behavior modification programs, such as smoking cessation or weight loss. Such programs must be comprehensive, evidence-based as determined by the Secretary, widely available and easily accessible. Finally, the option would explore ways to improve provider education and patient awareness of covered preventive services.

ACLA Comment: The Senate Finance Committee published Call To Action: Health Reform 2009 in November 2008. Under the section Coverage for Prevention in Federal Health Programs and Private Plan Options, the document referenced the need for participating plans to include preventive services “based on recommendations by appropriate entities such as the U.S. Preventive Services Task Force, the Advisory Committee on Immunization Practices, National Institutes of Health, Centers for Disease Control and Prevention, and Institute of Medicine.”

We concur with the November 2008 Senate Finance Committee recommendation to include several key government entities in addition to the USPSTF for determining preventive services and would urge inclusion of non-governmental organizations with expertise in evidence-based best practices to also be a resource in determining appropriate preventive services.

ACLA finds reliance solely on the USPSTF to determine the inclusion of preventive services a concern for patients and providers. As one of many examples to support this, the American Association of Clinical Endocrinologists recommend “Annually screen all individuals 30 years or older who are at risk for having or developing type 2 diabetes mellitus and screen all patients with diabetes mellitus for chronic kidney disease annually”. Neither of these measures for early detection of costly, chronic disease would be implemented under the current USPSTF recommendations. Provided as an attachment is a list of more examples demonstrating inconsistencies in the USPSTF recommendations as compared to evidence-based professional society recommendations for screening.

There is also a need to expand the USPSTF membership and mission. The current makeup of the USPSTF is limited to primary care physicians and should be expanded to include specialty physicians, public health professionals with screening test expertise, epidemiologists and biostatisticians. This expanded body should be charged by the Secretary to establish a separate workgroup of the USPSTF for the advancement of new, innovative genetic based screening test best practices. Membership on this workgroup should include molecular and genetic experts from the Association of Molecular Pathology, American College of Medical Genetics, American College of Obstetrics and Gynecology, College of American Pathologists, Genetic Alliance, Centers for Disease Control and Prevention and the Agency for Healthcare Research and Quality.

Further, the USPSTF preventive service recommendations, as expanded, together with preventive services recommendations from the other organizations named above, should be reviewed and approved by the National Quality Forum (NQF) consensus standards process for inclusion in CMS pay-for-performance incentives for primary health care providers. NQF is the leading government advisory body on healthcare quality measures and standards. NQF was created by both public and private sectors in 1999 as a recognized standards-setting organization under the Technology Transfer and Advancement Act. More than 350 organizations are NQF members representing every sector of the healthcare system. Major healthcare purchasers, including CMS and numerous private sector payers participate in the consensus standard process. Payers also rely on NQF endorsed measures

for pay for performance and reporting requirements, thus adding another important provider incentive element to the benefit program.