May 9, 2016

The Honorable Andy Slavitt
Acting Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Part B Drug Payment Model [Docket Number CMS-1670-P]

Dear Acting Administrator Slavitt:

As life sciences associations representing biotechnology, pharmaceutical, medical device and diagnostic companies, universities and research institutions, and venture capital firms across California, we are writing to express our serious concerns with the Centers for Medicare & Medicaid Services' (CMS) proposed rule that would implement a new "Medicare Part B Payment Model." This proposal, offered with only limited opportunity for input from stakeholders, would make sweeping changes to payment mechanisms for Medicare Part B covered drugs and directly and negatively impact California's most vulnerable seniors' access to life-saving therapies. Given the breadth of our concerns detailed herein and the adverse effects that will be directly felt by Medicare beneficiaries if these cuts were to be implemented, we respectfully request that CMS withdraw the proposed rule.

California is home to a thriving life sciences community with more than 2,800 companies and research institutions clustered throughout the state, whose efforts have led to groundbreaking therapies and technologies to diagnose, treat and prevent conditions such as cancer, cardiovascular disease, diabetes, HIV/AIDS, chronic pain, Alzheimer's, Parkinson's Disease, rare diseases, and others. In 2015, the most recent date for which full-year data is available, California companies advanced research and development into 1,235 new therapies – at least 366 of those medicines are to treat cancer. These companies share one core mission: the desire to improve the health and well-being of patients in need. Most life sciences companies are initially supported by the venture capital (VC) community, which helps provide the significant level of funding necessary to innovate and develop new cures and treatments for serious diseases. Without appropriate and predictable coverage and payment mechanisms, VC firms will be less willing to invest in expensive and high-risk biotechnology projects, cutting off the funding necessary to bring a new medicine or treatment to market. Imperative to the continued success of California's innovation ecosystem and its ultimate goal of providing patients with access to new, life-saving medical treatments and therapies is protecting coverage and access programs that are working– like Medicare Part B.

With enactment of the *Affordable Care Act*, Congress established and empowered the Centers for Medicare and Medicaid Innovation (CMMI) to test new methods of payment and service delivery models in healthcare to reduce spending – without sacrificing Medicare and Medicaid patients' access to treatment and services. Unfortunately, the Medicare Part B Payment Model unveiled by CMS on March 8, 2016 focuses solely on cost, rather than on quality and access to therapies for

Medicare patients. The draft rule proposes to implement a Medicare Part B drug reimbursement demonstration that would represent a substantial reduction to the current reimbursement scheme of Average Sales Price (ASP) + 6%, down to ASP + 2.5% with a flat $16.80 payment. Factoring in sequestration, reimbursement for Part B drugs under the demonstration would amount to ASP + 0.86% plus $16.80 – a dramatic cut in coverage and payment for these therapies. The proposal therefore not only undermines a key tenet of the mission of CMMI, but will undoubtedly lead to disruption in access to care for Californians who depend on Medicare services to treat complex conditions like cancer, rheumatoid arthritis, Crohn's disease, and rare diseases.

As reported in a recent Avalere study, CMS' proposed demonstration would disproportionally affect doctors who utilize more expensive drugs in their treatment of patients, including specialties like ophthalmologists, oncologists, and rheumatologists. In the proposed rule, CMS indicates their belief that the ASP + 6% reimbursement model may encourage the use of more expensive drugs to generate more revenue for providers. This assumption fails on the account that the specialties most impacted by this proposed demonstration often do not have a more affordable alternative to the drugs they administer to their patients.

Without adequate coverage and payment of these therapies, community physician practices will be forced to refer patients to hospital outpatient departments (HOPD), where the cost of care under Medicare is increased to the beneficiary. Patients will face reduced options for treatment and may be forced to travel long distances to receive care, posing a considerable barrier to treatment for the most vulnerable population of ailing Californians. Furthermore, researchers have routinely found that improved medication adherence—that is, getting people to take medicines prescribed for them—is associated with greatly reduced total health care use and costs. Imposing additional hurdles on patients to obtain care—such as forcing them to travel long distances for care, or pay higher out-of-pocket costs for treatment—will undoubtedly increase medicine non-adherence, thus decreasing health outcomes and driving up health care costs when a patient incurs hospitalizations and emergency department visits.

As representatives of California's innovative life sciences research and development community, we believe this misguided policy will put at risk the promise of existing and future therapies and gravely impede California's seniors' access to life-saving drugs. We therefore again respectfully request that CMS permanently withdraw the proposed Part B Drug Payment Model rule.

Should you have any questions or to discuss our views further, please contact Jenny Carey, CLSA's vice president of federal government relations and alliance development (jcarey@califesciences.org or 202.743.7559).

Sincerely,

Sara Radcliffe, President & CEO, CLSA

Greg McKee, President & CEO, Connect

Joseph D. Panetta, President & CEO, Biocom

Ahmed Enany, President & CEO, SoCalBio