PERSONALIZED MEDICINE COALITION

December 21, 2018

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Attn: CMS-1701-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-8013

**RE: Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM)**

Dear Administrator Verma:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprised of more than 230 institutions and individuals across the health care spectrum, is writing to express concern with the recent Advance Notice of Proposed Rulemaking (ANPRM) released by the Centers for Medicare & Medicaid Services (CMS) detailing actions the Administration is considering to establish an International Pricing Index (IPI) Model for Medicare Part B drugs.[i] PMC appreciates the opportunity to comment on the ANPRM, as we believe that this proposed model would negatively impact personalized medicine. Instead of proceeding with the IPI Model, which may impede innovation and disrupt patient care by focusing solely on short-term tactics to lower drug costs, we urge CMS to utilize the Center for Medicare and Medicaid Innovation (CMMI) to advance Part B delivery models with a longer-term view of reducing overall health care costs by aligning provider incentives with strategies that guide patients to the most appropriate treatment for them.

Personalized medicine is an evolving field that uses diagnostic tools to identify specific biological markers, often genetic, to help determine which medical treatments and procedures will be best for each patient. By combining this information with an individual's medical history, circumstances, and values, personalized medicine allows doctors and patients to develop targeted prevention and treatment plans. Personalized medicine is helping to shift the patient and provider experience away from trial-and-error and toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

The health care delivery system in the United States is not currently structured to consistently deliver personalized medicine to all patients who may benefit from it, so PMC generally supports CMS' interest in testing new delivery and payment models. We have shared previously with CMS that we believe new models must support innovation; enhance the alignment of incentives; incorporate key perspectives to define high-value care; focus on outcomes that matter to patients; and construct efficient arrangements between payers, drug manufacturers, and other stakeholders.[ii] The IPI Model for Medicare Part B described in the ANPRM is not a model we can support when viewed through this lens. We briefly highlight several concerns with the IPI Model below.

**Statement of Neutrality**

Many of PMC's members will present their own responses to CMS on the ANPRM for the Medicare Part B Drug IPI Model and will actively advocate for their positions. PMC's comments are not intended to impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments and positions.

**The IPI Model Could Negatively Impact Innovation**

In an effort to lower the price of some medications in the United States, the IPI Model, as we understand it, would use prices in 14 countries as a benchmark for deciding what Medicare would pay for certain Part B drugs. The Medicare Modernization Act of 2003 defined an average sales price (ASP) that the government will pay for Part B drugs. This ASP already includes 15 to 35 percent discounts off a drug's list price on average.[iii] Many of the countries mentioned in the ANPRM peg their payments for medications to other countries, while others assess the cost-effectiveness of medications and limit how much they will pay for expected gains in the length and quality of life. Experts looking at the free-market system of drug pricing estimated in 2008 that there was a 15 percent reduction in research and development spending in countries where these practices were in place. A 15 percent reduction in spending during the period covered by their research would have resulted in 117 fewer new medicines being developed in the U.S.[iv]

The current structure of the pharmaceutical market in the U.S. has produced highly innovative and personalized therapies that have had a positive impact on patient care. A July 2018 analysis by Charles River Associates shows that personalized medicine is delivering better efficacy, improvements in overall survival, and a reduction in adverse events for patients. [v] In January of 2018, PMC released *Personalized Medicine at FDA: 2017 Progress Report*, which documents a record number of new personalized medicine approvals by the U.S. Food and Drug Administration (FDA). This marks the fourth consecutive year that personalized medicines accounted for more than 20 percent of all new drug approvals.[vi] Two of the 19 personalized medicines approved in 2017 were CAR T-cell therapies, by which a patients' immune cells are collected and genetically changed to treat his/her cancer. Transformative therapies like these are the result of decades of research in biology, genetics, and immunology supported by the National Institutes of Health and the biopharmaceutical industry. A study conducted by the Massachusetts Institute of Technology NEWDIGS FoCUS Project predicts that in the current environment there will be about 40 gene therapy products approved by the FDA by 2022, with 45 percent of these for products targeting cancer. [vii]

Economists have noted that that a 50 percent drop in drug prices could lead to a 14 to 24 percent decrease in the number of drugs in the development pipeline.[viii] Approximately 90 percent of clinical programs fail to lead to FDA approvals.[ix] For challenging disease areas where failure rates are higher than average, like Alzheimer's disease[x] and individualized cell and gene therapies, which force companies to take risks and leverage cutting-edge science, a significant reduction in the pipeline could be devastating to patients in need of therapeutic options.

**The IPI Model is Inconsistent with CMMI's Purpose**

In 2017, PMC provided feedback to CMS on its request for information (RFI) on new directions for CMMI.[xi] In our response, we commended CMS for re-examining CMMI's guiding principles since CMMI had previously been used to impose large, national, mandatory payment and delivery models that were difficult to implement and focused more on reducing cost than improving outcomes that matter to patients. Our RFI comments cautioned that continued proposals imposing blunt payment cuts or rigid clinical or cost-effectiveness standards would create significant barriers to the development of and access to innovative drugs and diagnostics. An analysis of the European landscape for personalized medicine showed that countries with more strict health technology assessment methodology and cost-effectiveness thresholds, like England, experience more restricted reimbursement and access to personalized medicine.[xii] Rather than continuing down a similar path to contain costs, we urged CMS to support a more effective and efficient health system through the development of payment models that align with the principles of personalized medicine, and, by extension, with high-quality, patient-centered care, which has the power to improve outcomes and deliver value to the health system.

CMMI was created by Congress to develop, test, and implement new payment and delivery models. These models should be mechanisms to drive value while promoting individualized care integration, not a means to impose "one-size-fits-all" treatment approaches that can undermine a patient's ability to access targeted care. Unfortunately, the ANPRM describes the IPI Model as a large, national, mandatory model with an immediate impact on half of the population of people using Medicare Part B drugs, many of which are personalized medicines.

PMC believes this proposal will jeopardize patient care and is inconsistent with CMMI's mandate to test innovative payment and service delivery models that preserve or enhance quality. This proposal signals resistance within CMS to address stakeholder comments submitted during the RFI process that would help CMMI chart a new course by fostering the adoption of personalized medicine. PMC believes that personalized medicine can help CMS deliver affordable, accessible health care that puts patients first, but that will happen only if models of care allow providers the flexibility to maximize individual patient outcomes by tailoring care.

**The IPI Model May Influence Provider Decision-Making**

The IPI Model would pay providers a fixed fee for administering Part B infusion and injectable drugs as opposed to the current Part B program arrangement which sets payment rates based on the ASP negotiated for the drugs in the market plus a six percent add-on payment. The Administration has framed the fixed fee payment as a way to remove incentives for physicians to prescribe a more expensive drug rather than a less expensive alternative. The fixed fee payment in the IPI Model is based on criticism that many physician-administered drugs for the same condition offer similar efficacy and

side effect profiles to other drugs that treat the same condition, and that physicians prescribing physician-administered drugs in these instances are guided by financial incentives rather than the clinical needs of their patients.

A report released in September of 2018 tested the hypothesis that prescribers of physician-administered drugs disproportionately prescribe therapies with higher reimbursement rates to financially benefit from add-on payments. The report found that for breast cancer and non-small cell lung cancer, two diseases for which important personalized treatments exist and use of physician-administered Part B drugs is prevalent, less than one percent of the variation in utilization of physician-administered Part B drugs can be attributed to higher payment rates. The authors conclude that other factors beyond payment play a significant role in driving prescribing.[xiii] They contend that policy proposals based on the premise that payment rates influence physician utilization patterns in Part B may significantly overestimate anticipated savings from changes in reimbursement.

Many physicians argue that medicines to treat the same disease are not always interchangeable, and their prescribing is guided by the best available evidence on the safety and effectiveness of medicines and the needs and values of individual patients. Without additional detail on how the fixed fee payment will be calculated and how the change in payment correlates with patient outcomes, we are concerned that this attempt to remove incentives for prescribing more expensive Part B drugs may instead create a situation in which the system is incentivizing low-value care when that is less costly to providers.

A significant proportion of the targeted therapies on the market and those arriving in the clinic require patients to have essential tests as part of a drug's indication. There are also many complementary diagnostics that support treatment decisions but are not essential prior to prescription.[xiv] PMC believes that exploring payment models incorporating diagnostic strategies that optimize the benefits of Part B medications is an important first step for CMS to take before altering Part B payment arrangements in ways that may be detrimental to the delivery of personalized medicine.

**Conclusion**

We recognize the increasing pressure to contain overall health care costs and we hope CMS recognizes that personalized medicine is part of the solution. PMC urges you to pursue solutions that bring us closer to the goal we share with you of delivering appropriate, efficient, and accessible health care to every patient. PMC welcomes the opportunity to serve as a resource for you. If you have any questions about the content of this letter, please contact me at 202-589-1769 or cbens@personalizedmedicinecoalition.org.

Sincerely,

Cynthia A. Bens
Senior Vice President, Public Policy

CC: Alex M. Azar II
Secretary
Department of Health and Human Services

Adam Boehler
Deputy Administrator for Innovation & Quality
Director
Center for Medicare and Medicaid Innovation

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[i] Centers for Medicare & Medicaid Services. (2018, October 30) Advance Notice of Proposed Rulemaking Medicare Programs: International Pricing Index Model for Medicare Part B Drugs (CMS-5528-ANPRM) https://www.regulations.gov/document?D=CMS-2018-0132-0001

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