January 25, 2019

The Honorable Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

SUBMITTED ELECTRONICALLY VIA REGULATIONS.GOV

RE: Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses (CMS-4180-P)

Dear Administrator Verma:

On behalf of the National Marrow Donor Program® (NMDP)/Be The Match®, we thank you for the opportunity to provide our comments on the proposed rule entitled, "Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses."

For the thousands of Americans diagnosed every year with life-threatening blood cancers like leukemia and lymphoma, a cure exists. NMDP manages the largest and most diverse marrow registry in the world through a competitively-bid contract with the Health Resources and Services Administration (HRSA). Each year, the Congress appropriates funds to operate this federal program, which is designated by the Congress as the C.W. Bill Young Cell Transplantation Program (Program). Since the mid-1980s, Congress has reauthorized the Program with virtually unanimous support. Today, there are 19 million U.S. volunteers listed on the registry that are willing to donate, in addition to more than 249,000 cord blood units, making the cure available through transplant a reality for thousands of Americans each year.

As the steward of this critical federal public health program, we work to identify and eliminate barriers faced by those patients in need of one of these life-saving transplants. In addition to being a core component of our contracts with HRSA, assisting with third-party payer matters is a function of the Office of Patient Advocacy as outlined by Congress in the statute authorizing the Program. NMDP also partners with nearly 200 hospital transplant programs in assisting them with efforts to protect access to transplant.

NMDP supports the Centers for Medicare and Medicaid Services' (CMS) goals of lowering drug costs and reducing out-of-pocket costs for patients, but we are concerned that the proposed changes will disrupt timely patient care and could create barriers for patients in accessing appropriate therapies. The NMDP urges CMS to reconsider the exemptions to the protected class policy to ensure that patients continue to have access to appropriate therapies.

Through the Office of Patient Advocacy, NMDP has an obligation to ensure that patients have access to allogeneic hematopoietic stem cell transplant (HCT). NMDP provides the following

comments to detail our concerns with the proposed rule that would create a barrier for the vulnerable population of patients who receive allogeneic HCT.

1) **NMDP opposes broader use of prior authorization (PA) and step therapy (ST) for protected class drugs**

The NMDP opposes applying utilization management tools for protected class drugs, including chemotherapy and immunosuppressive drugs, which are critical therapies for patients who receive allogeneic HCT. Applying PA and ST will create delays for patients for whom these medications are necessary to their treatment and continuity of care. Patients have typically exhausted other treatment options before becoming candidates for HCT to treat their blood cancer or blood disorder. Requiring these patients to step through several treatments or therapies before being able to access their needed chemotherapy or immunosuppressive drug not only delays access to the most optimal treatment for their disease, but also may result in poor outcomes, poor overall health, and poor patient quality of life.

Protected class drugs were established to "ensure that Medicare beneficiaries reliant upon these drugs would not be substantially discouraged from enrolling in certain Part D plans, as well as to mitigate the risks and complications associated with an interruption of therapy for these vulnerable populations[1]." We urge CMS to continue to maintain these protections, as mitigating risks and complications associated with an interruption of therapy remains critically important for vulnerable patients who rely on these medications every day.

2) **NMDP opposes the proposed exemption to exclude a protected class drug from a formulary if the drug represents only a new formulation of an existing single-source drug or biological product, regardless of whether the older formulation remains on the market**

The NMDP opposes this proposed exemption for the same reason as above; exclusions from formularies could create barriers for patients in accessing appropriate therapies, especially for the patients for whom their access to an essential treatment would be completely removed.

3) **NMDP opposes the proposed exemption to exclude a protected class drug from a formulary if the price of the drug increased beyond a certain threshold over a specified look-back period**

Similarly, the NMDP opposes this proposed exemption; exclusions from formularies based on price alone neglect clinical appropriateness and efficacy of treatment. Again, this could create barriers for patients who rely on these treatments as an essential part of their care.

For the same reasons detailed above, NMDP opposes allowing Medicare Advantage (MA) plans to apply step therapy as a utilization management tool for Part B drugs.

Thank you again for providing us with the opportunity to provide comments on the proposed rule, Modernizing Part D and Medicare Advantage to Lower Drug Prices and Reduce Out-of-Pocket Expenses. We welcome the opportunity for discussion with the Agency on these important issues that impact patient access to life-saving care. If you have any questions,

[1] https://www.cms.gov/Medicare/Prescription-Drug-coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf

please free to contact me with any questions at blindber@nmdp.org or (763) 406-8566 or Susan Leppke, Director, Health Policy at sleppke@nmdp.org or (763) 406-8522.

Sincerely,

Brian L. Lindberg, JD
Chief Policy Officer