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January 16th, 2018

Ms. Seema Verma
Administrator
Center for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to: http://www.regulations.gov/

RE: Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program (CMS-4182-P)

Dear Administrator Verma:

On behalf of the Global Healthy Living Foundation (GHLF), thank you for the opportunity to submit comments on CMS's proposed rule "Medicare Program; Contract Year 2019 Policy and Technical Changes to the Medicare Advantage, Medicare Cost Plan, Medicare Fee-for-Service, the Medicare Prescription Drug Benefit Programs, and the PACE Program" (Part D rule).

GHLF is a 501(c)(3) patient advocacy organization that works to improve the quality of life for people living with chronic disease by making sure their voices are heard. GHLF represents more than 100,000 chronically ill patients and their caregivers across the country who are members, and millions more who are exposed to our social and conventional media outreach. We advocate for improved access to care at the community level and represent Americans suffering from chronic conditions such as autoimmune diseases, chronic pain, cancer, diabetes, cardiovascular disease, migraines, and psoriasis.

We strongly support the Agency's efforts to explore ways to decrease the financial burden on beneficiaries. In particular, we applaud the inclusion of the proposed rule's section entitled "*Request for Information Regarding the Application of Manufacturer Rebates and Pharmacy Price Concessions to Drug Prices at the Point of Sale*." For far too long, attempts to reduce health care costs have not been made with end consumers - the patient community - in mind. Pharmacy Benefit Managers (PBMs), wield too much power in determining patient healthcare access and cost, and negotiations between PBMs and insurance companies occur behind closed doors with people rarely seeing the benefits from these conversations, either financially or therapeutically.

GHLF supports a 100 percent mandatory rebate pass-through policy and endorses the comments submitted by the Alliance for Transparent and Affordable Prescriptions (ATAP) on this request for information (RFI). A 100 percent mandatory pass-through policy would result in a significant decrease in patient costs, as shown by CMS's impact estimates. In order to ensure that this pass-through policy is

effective, GHLF believes strongly that there should be a requirement for a definitional agreement for certain terms that are frequently used by PBMs. This will stop these entities from gaming the system by reclassifying money and avoiding pass-through obligations.

The promise of savings garnered from negotiations contributing to lower premiums and deductibles has not come to fruition. We must bring the pharmacy benefit in line with hospital and physician outpatient benefits. Patients in our community walk into their physician office or hospital and they have a coinsurance/copayment or deductible. They pay those out-of-pocket costs based on the negotiated price, not the retail price. Our community members ask, why is it different for prescription drugs?

GHLF understands that a 100 percent pass through rate may result in slightly higher premiums, but we feel that in the end, the actual savings patients would see from the reduction in out-of-pocket costs for prescriptions would result in overall lower costs for them. While consumers may be drawn to plans that have lower premiums, the high out-of-pocket costs they pay for prescriptions means they almost certainly will be worse off financially.

GHLF was also encouraged by the provisions in the section titled "*Maximum Out-of-Pocket Limit for Medicare Parts A and B Services*." Data analysis have shown that 10 percent of Medicare beneficiaries account for almost 60 percent of spending.[1] As such, we encourage CMS to reconsider the percentiles used as benchmarks for calculating maximum out of pocket (MOOP) spending. The existing methodology of using the 85th and 95th percentiles of projected beneficiary out-of-pocket Medicare spending does not account for those who are experiencing the highest costs, many of whom are a part of our patient community, and who are the most in need of financial relief. These individuals are relying on a healthcare system that currently has the sick subsidize the healthy. This is not the way insurance was intended to function. Our patient-powered research network, ArthritisPower, works to gather data about the patient experience, which we believe can be useful when considering financial impact on patients into policy decisions. GHLF appreciates the Agency's commitment to a transparent approach to this revaluation and plans to take advantage of opportunities to weigh-in on proposed changes to MOOP calculations before they take effect.

Many of our patients have seen incredible benefits from innovative biologics, and we are hopeful that as biosimilars enter the market, more patients will have access to the promise of these treatments. We are well aware that biosimilars are not generics and have advocated to FDA and CMS on several instances that they should not be treated as such. However, in this specific instance we support the Part D rule's proposal to treat biosimilars as generics for catastrophic cost-sharing policies as stated in "*Treatment of Follow-On Biological Products as Generics for Non-LIS Catastrophic and LIS*". We've taken this position because we believe it is in the best interest of the patient as the classification of biosimilars as generics for cost-sharing purposes will provide enrollees with incentives to choose these options which will result in a reduction of cost to both the beneficiaries and the Part D program.

[1] Juliette Cubanski, et al. "A Primer on Medicare: Key Facts About the Medicare Program and the People It Covers - How Much Does Medicare Spend, and How Does Current Spending Compare to Past Trends and the Future Outlook?" The Henry J. Kaiser Family Foundation, 31 Mar. 2016, www.kff.org/report-section/a-primer-on-medicare-how-much-does-medicare-spend/.

Additionally, we support provisions of the proposed rule that would prohibit plans from excluding non-preferred generic drug tiers from tiering exceptions, as laid out in "*Part D Tiering Exceptions*" section. GHLF has worked tirelessly to pass step therapy legislation in nearly 20 states to reform the insurance appeals process and reduce barriers-to-access for our patients, and we support H.R. 2077, the "*Restoring Patients' Voice Act of 2017*", the corresponding Federal effort championed by Representatives Brad Wenstrup (R-OH) and Raul Ruiz (D-CA). We suggest that CMS consider adopting some of the core principles of this policy in its tiering exceptions section which requires insurers to respond to appeals in 72 hours, or 24 hours in emergency situations. Should insurers not respond within that timeframe, we would encourage CMS to consider the appeal as approved.

Finally, we would like to thank the Agency for the steps laid out in the proposed rule to address the opioid epidemic. Many of the patients we represent are suffering from chronic pain and while for some, opioids may be the only source of relief that allows them to lead productive lives, we are acutely aware of how quickly patients can become susceptible to addiction and the dangers these drugs pose to our society. As a member of the Consumer Pain Advocacy Task Force, our organization has been a vocal advocate for policies aimed to reduce this problem. The implementation of the statutory provisions in the Comprehensive Addiction and Recovery Act of 2016 is a strong step towards this goal. GHLF also supports the reauthorization of the National All Schedules Prescription Electronic Reporting Act. We encourage the Agency to build on these efforts by issuing policies that increase use of prescription drug monitoring programs and to work with other Agencies to implement recommendations from the Institute of Medicine's National Pain Strategy Plan. It is our hope that together, these policies will educate the public, mitigate risks associated with opioid usage, and work to end the epidemic of addiction.

In conclusion, GHLF remains committed to advocating for policies that center on the patient experience and are pleased with many of the provisions in the proposed Part D rule. Once again, thank you for the opportunity to provide these comments. We look forward to continuing to work with the Agency to make innovation treatments accessible to patients. If GHLF can be of any assistance as you consider stakeholder feedback and plan next steps, please contact me at smarmaras@ghlf.org or my cell at 203-470-9309.

Respectfully,

Stephen Marmaras
Director, Policy and Advocacy
Global Healthy Living Foundation