April 8, 2016

Andy Slavitt, Acting Administrator
Centers for Medicine & Medicaid Services
200 Independence Ave., SW
Washington, DC 20201

Dear Acting Administrator Slavitt,

The undersigned organizations write to request that the Centers for Medicare & Medicaid Services (CMS) review and consider revising its policies to ensure that Medicare, Medicare Advantage, Medicare Part D, Medicaid, and Marketplace patients with hepatitis C virus (HCV) have access to all physicians that have the expertise to treat them. We believe that treatment for chronic HCV should be based on the prescribing physician's expertise rather than a requirement of medical specialist consultation.

According to a 2013 *CDC* Surveillance report from November 2013, an estimated 3.2 million persons in the United States are living with HCV infection. Historically, hepatitis C treatments were administered by self-injection of interferon (IFN). These injections had terrible side effects and only a 50 percent cure rate. The cost ranged from $15,000 to $20,000 depending on the length of treatment. Now, the latest treatments have a 90 percent cure rate and few side effects. Harvoni (Ledipasvir/sofosbuvir), one of those most recently approved, is one oral pill each day. However, the cost is $1,125 per pill. That means a two-month supply is approximately $63,000, a three-month supply is $94,500 and a six-month supply is $189,000, as reported in a *Hepatitis Central* article.

When hepatitis C treatments were very complicated and toxic, there were no restrictions on who could prescribe those extremely complex drugs. Prescriber restrictions are only now being added as newer and more effective medications with fewer side effects that are easily administered in oral form have come to the market. For example, according to a study in the *Annals of Internal Medicine* which examined Medicaid reimbursement criteria for Sovaldi (Sofosbuvir) in all 50 states and the District of Columbia, "twenty-nine states have restrictions based on prescriber type. In 14 states, the prescriber has to be a specialist (gastroenterology, hepatology, infectious diseases, or liver transplantation), whereas in 15 states treatment decisions can be made by a non-specialist after consultation with a specialist." The decision to restrict the ability to prescribe treatment for HCV is particularly problematic in light of potential shortages in the designated specialties. According to Becker's GI & Endoscopy, it is estimated that by the year 2020, there will be a shortfall of somewhere between 1,000 to 1,500 practicing gastroenterologists alone in the United States. The shortage of medical subspecialists in general is estimated to be between 3,200 and 8,400 by 2020 according to the Association of American Medical Colleges (AAMC) report, *The Complexities of Physician Supply and Demand: Projections from 2013 Through 2025*.

Prescriber restrictions particularly disadvantage patients living in rural areas. According to the 2010 U.S. census, about 20 percent of the population lives in rural areas while nine percent of physicians practice there. The distribution of physicians in rural and urban settings is also unequal with more physicians choosing to work in urban settings for a variety of reasons. The more highly specialized the physician, the less likely he or she will settle in a rural area, as stated in an article regarding physicians and rural America. However, acute hepatitis C infections rose by 150 percent between 2010 and 2013, with the largest increase in rural areas, according to the Centers for Disease Control and Prevention. Consequently, restrictions on

HCV treatment that mandate prescription by or consultation with a specialist rather than by a qualified primary care physician disadvantage patients in rural areas, since they often have less access to such specialists.

Finally, the restrictions on HCV treatment in question ignore the fact that primary care physicians with the appropriate education and experience have been treating patients with HCV for years. Only recently, when costly new drugs became available, did new restrictions occur.

Our organizations oppose actions by public and private payers that limit patients' access to HCV treatment pharmaceuticals prescribed by a physician using appropriate clinical training and knowledge and oppose any actions by public or private health insurers that may have the effect of limiting by specialty the use of HCV pharmaceutical products. Thus, we ask CMS to ensure that neither Medicare (including Medicare Advantage and Medicare Part D) nor Medicaid discriminates against physicians in the treatment of patients with hepatitis C virus (HCV) based on physician specialty.

We are aware that CMS has issued a notice to state Medicaid directors, warning them that they might be violating federal law by denying hepatitis C drugs to patients and expressing concern that some states are preventing access to hepatitis C drugs contrary to federal law by "unreasonably" imposing limitations that lack clinical relevance. We appreciate CMS's efforts in this regard and encourage the agency to continue to monitor the situation as it relates to Medicaid. Similarly, we believe that limiting such prescribing in Medicare Advantage, Medicare Part D, and Marketplace plans to certain physician specialties will harm patients' access to timely and effective care.

We appreciate your time and attention to this matter. If you or your staff have any questions about this or if we can provide any other assistance, please contact Robert Bennett, AAFP Manager of Federal Regulatory Affairs, at 202-232-9033 or rbennett@aafp.org.

Sincerely,
American Academy of Family Physicians
American College of Osteopathic Family Physicians
American College of Osteopathic Internists
American College of Physicians
American Gastroenterological Association
American Osteopathic Association
HIV Medicine Association
Infectious Diseases Society of America