The undersigned organizations representing physicians thank the Centers for Medicare and Medicaid Services (CMS) for its attention to the negative impacts of high drug prices on Medicare and Medicaid beneficiaries, physicians, and the health care system. However, we have serious concerns about CMS’s recent notification to Medicare Advantage plans that they will no longer be prohibited from utilizing step therapy protocols for physician administered drugs covered under Medicare Part B beginning in 2019. We find the growing trend towards the use of restrictive and burdensome utilization management tactics by payors concerning and urge CMS to reconsider its stance on this critical patient care issue.

Step therapy protocols that require patients to try and fail certain treatments before allowing access to other, potentially more appropriate treatments can both harm patients and undercut the physician-patient decision-making process. The most appropriate course of treatment for a given medical condition depends on the patient’s unique clinical situation and the care plan developed by the physician in close consultation with that patient. While a particular drug or therapy might be generally considered appropriate for a condition, the presence of comorbidities or patient intolerances, for example, may necessitate the selection of an alternative drug as the first course of treatment. Step therapy requirements often fail to allow for such considerations, resulting in delays in getting patients the right treatments at the right time and unnecessary complications in the physician-patient decision-making process.

While step therapy protocols are problematic for many patients on a variety of therapies, they are particularly concerning where physician-administered drugs are concerned. In many cases, patients receiving drugs covered under Part B are especially vulnerable, many with serious or life-threatening conditions. Many cancer therapies, for example, are covered under Part B. For cancer patients, selecting the proper personalized treatment as quickly as possible can be critical to survival. For others, such as those suffering from conditions like autoimmune disorders and progressive blinding eye diseases, delays in getting appropriate treatments can mean prolonged symptomatic periods and irreversible damage, making a “fail first” approach to treatment inappropriate. Although the notification states that step therapy can only be applied to new prescriptions and administrations of Part B drugs, we have serious concerns about patients who will change Medicare Advantage plans being required to disrupt their current treatment to retry previously failed therapeutic regimens to meet step therapy requirements for a new plan. We also note that many Part B drugs are periodically infused, compared to being administered on a routine basis, which could easily lead to different interpretations between plans in what is considered a “newly prescribed” medication and to interruptions in ongoing therapy that could have devastating, permanent consequences for Medicare beneficiaries and their health.

Step therapy likewise places a significant administrative burden on physician practices. Physicians do not currently have ready access to patient benefit and formulary information, as there is currently no capability making this information available through electronic health records or other means at the point of prescribing. This lack of transparency makes it exceedingly difficult to determine what treatments are preferred by a particular payor at the point of care and places practices at financial risk for the cost of administered drugs if claims are later denied for unmet (yet unknown) step therapy requirements. Furthermore, payor exemption and appeals processes can be complicated and lengthy, making them burdensome for both busy physician practices and patients awaiting treatment. At a time, when CMS has prioritized regulatory burden reduction in the patient-provider relationship through its Patients Over Paperwork initiative, it is our hope that another layer of administrative complication will not be added on to an already strained system.

As rising drug prices continue to place huge financial burdens on patients and the health care system, we recognize the significant difficulty of finding meaningful solutions that have the desired outcome of reducing costs for both. However, as we work towards finding policies to address this problem, we hope that solutions can be found that do not involve the creation of barriers to appropriate and timely treatment for some of our most critical patients. Given this, we urge CMS to reinstate its 2012 policy prohibiting Medicare Advantage plans from utilizing step therapy protocols for Part B physician administered medications. We look forward to working with CMS to find a better path forward for physicians and patients.