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The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Secretary Azar:

The American Society for Gastrointestinal Endoscopy (ASGE) welcomes the opportunity to comment on "American Patients First: The Trump Administration Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs" and the corresponding request for information. For providers, the high cost of drugs has set up an elaborate system by vendors, insurance companies, and manufacturers to control and manipulate costs. This elaborate system causes excessive burden to the physicians trying to provide the best and most appropriate care, leading to physician burnout from more time dealing with third-party intermediaries and less with providing patient care. As the Administration considers options for making drugs more affordable, we ask that it most immediately address the administrative burdens and inefficiencies of the current system on physicians and patients.

The ASGE was founded in 1941 and since that time has been dedicated to advancing patient care and digestive health by promoting excellence in gastrointestinal endoscopy. ASGE, with more than 14,000 members worldwide, promotes the highest standards for endoscopic training and practice, fosters endoscopic research, recognizes distinguished contributions to endoscopy, and is the foremost resource for endoscopic education.

It is important for policy makers, both state and federal, to comprehensively address barriers that impede access to health care in this country. The cost of drugs and its contribution to the overall cost of care is worthy of a multi-faceted examination, which should include drug pricing, including the effect of drug shortages on pricing. While drug prices are straining the health care system and access to affordable care, lowering the cost of drugs alone will not make health care more accessible for individuals and families who are unable to afford health insurance. ASGE sharply disagreed with the Administration's decision to end low-income cost sharing subsidies and is troubled with the Department of Justice's decision to not defend the Affordable Care Act (ACA) in the lawsuit filed by Texas and other states. If the plaintiffs in the suit are successful, important provisions

of the ACA, such as protections for pre-existing conditions and coverage of preventive benefits, will be null and void. Both these actions have the significant potential to limit health care access.

The blueprint includes two policy ideas that, if instituted, have the potential to add to the already high level of regulatory and administrative burden that physicians must shoulder and to hinder patient access to prescribed therapies: 1) expanding the government's competitive acquisition program (CAP) authority; and 2) moving select Part B drugs into Part D.

Gastroenterologists treat disorders of the bowel that produce an inflammatory response and for which biologics, oftentimes administered in the physician's office and reimbursed under Part B, are the primary treatment. Therefore, any changes to the way in which Part B drugs are acquired and reimbursed will have a significant effect on gastroenterologists and their patients.

Competitive Acquisition Program

The blueprint suggests that physicians would have a choice between obtaining Part B drugs from vendors selected through a competitive bidding process or directly purchasing these drugs and being paid under the current average sales price (ASP) methodology. If a CAP is being imagined as voluntary, it is difficult to understand why physicians wouldn't again reject this approach as they did previously, unless the Administration's goal is to eliminate the ASP payment methodology — an approach ASGE does not support at this time.

The practice of medicine requires flexibility. The CAP, or a model building on CAP authority, could impede the ability of physicians to deliver treatment, specifically tailored to the patient, in a timely manner. For example, under the original CAP physicians were required to place an order for a specific treatment with the CAP vendor in advance of the patient's visit, and drugs could not be stored. This process limits the ability of a physician to adjust a treatment plan between diagnosis and administration of treatment. It is not uncommon for patients to change appointment dates on short notice; therefore, physician offices and infusion centers need flexibility with ability to store medications. Sometimes, clinical deterioration requires use of a higher initial or earlier subsequent dose of specialty drugs; it doubtful that the CAP process is flexible enough for these circumstances. Providing appropriate flexibility to allow for changes in clinical scenarios and ensuring that physicians who administer Part B drugs are fairly compensated for their overhead costs are two important considerations for a future CAP or similar program.

More importantly, physicians are wary of any design that will make it more difficult for them to access the treatments they have prescribed. For a CAP to succeed, third-party vendors must find it attractive to participate and be given the right negotiating tools, which could include the use of restrictive formularies and, consequently, impediments to patient care. Biological therapies can lose effect over time due a patient's immune reaction, necessitating a drug change within a class. Because biologics within a class (such as an anti-TNF) are not equivalent, vendors would need to be directed by CMS to be more inclusive, rather than restrictive, in the number of drugs, including biosimilars, for this class and include a rapid appeals process for drugs that fall outside a formulary. Other concerns include insurance plans or pharmacy benefit managers switching brands or switching a patient between name brand and generic labels with little notice, even for

biosimilars. This is not an appropriate practice and should not be permitted under a CAP or similar program.

We also want to raise the question of how a CAP approach would work if a drug became in short supply. The current ASP methodology allows physicians to be somewhat nimble when dealing with the unexpected.

Moving Part B Drugs into Part D

Among ASGE's primary concerns, based on gastroenterologists' experiences with Part D plans, are the imposition of utilization controls that interfere with physician-patient decision making and cost to patients. ASGE urges the Administration to work with providers to address these barriers and their associated administrative burden rather than exacerbate the problem moving Part B drugs into Part D.

Under Part D and other private insurance plans, complex drugs, including biologics covered by private plans, are uniformly subject to complex authorization processes that involve substantial delays in treatment. Gastroenterologists routinely have to utilize specialty pharmacies or authorization specialists to navigate the authorization requirements. ASGE members also frequently run into the need to prove that a patient failed other therapies, including sometimes one or more drugs in the same category, before the requested therapy will be approved. Physicians are not given rules or indications of how these authorizations will be adjudicated. Frequently — an estimated 30-50 percent of the time — the way a gastroenterologist needs to use a biologic doesn't fit the Food and Drug Administration's initial indication and may be denied or delayed for one or more levels of appeal, including appeal to outside peer review. For example, some individuals with Crohn's disease should have a higher dose infliximab — 10mg/kg, not 5mg/kg — even for initial therapy, or step up because of incomplete or failing responses. As another example, treatment of Crohn's disease may require weekly, instead of bi-weekly, administration of adulimumab; others need a repeat induction dose of medication to re-capture response.

Private plans also commonly deny coverage for measuring therapeutic drug levels, or the fecal lab test (calprotectin) most useful for monitoring the degree of response or lack of response; making it very difficult to know in whom to adjust drug dose or to change drugs. We would insist that clinicians would have input into the proposed treatment and monitoring algorithms to maximize safety and value to our patients.

As mentioned above, because there are no biologic equivalents, requiring Part D plans to only cover two medicines per class is ill-suited for this class of medication.

Additionally, shifting drugs from Part B to Part D is likely to increase out-of-pocket costs to Medicare beneficiaries and, in some cases, making the drug cost-prohibitive. The majority of Part B beneficiaries have supplemental coverage that helps with their coinsurance. Allowing Part B medications to shift to Part D, where cost sharing for specialty medicines could significantly increase costs for those Part B beneficiaries. Any move of a drug from Part B to Part D should be subject to a public review and comment process, with an examination of the effect the shift

would have on patient out-of-pocket costs and the ability of a physician to administer medications in the office where appropriateness is clear.

Indication-based Pricing

A question raised in the blueprint is whether Medicare or Medicaid should pay the same price for a drug regardless of the diagnosis for which it is being used. In this regard, ASGE affirms its support for current policy of the American Medical Association which states that value-based prices of pharmaceuticals must be evidence-based and be the result of valid and reliable inputs and data that incorporate rigorous scientific methods, including clinical trials, clinical data registries, comparative effectiveness research, and robust outcome measures that capture short- and long-term clinical outcomes. AMA policy also states that processes to determine value-based prices of pharmaceuticals should incorporate affordability criteria to help assure patient affordability, as well as limit system-wide budgetary impact; and should allow for patient variation and physician discretion. In addition to outcomes, other inputs can include: cost, efficacy, comparative effectiveness research, toxicity/side effects, novelty, budgetary impacts, incremental cost-effectiveness, and impacts on patients such as long-term benefits, patient individual budget, impact of caregivers, and returning to work.

Gastroenterologists already encounter many roadblocks getting off-label tests and treatments approved by private insurance plans, and there are long time lags between centers of excellence introducing new tests and treatments and when health plans will approve payment. For example, as mentioned above, gastroenterologists have difficulty getting health plan approval of fecal calprotectin as a method of assessing response to drug effects. Payers have also resisted covering the off-label use of Stelera and Xeljanz to treat psoriasis for patients with Crohn's disease or ulcerative colitis, respectively, even though there are phase III studies showing benefit (these now have FDA indication for Crohn's and for ulcerative colitis, respectively).

Site Neutrality for Physician-administered Drugs

ASGE opposes the concept of establishing "site neutral" payment policies. Payment inequity among sites of service has been exacerbated by years of payment cuts and unpredictability, which has led to shifts in where gastroenterology and other services are provided. Payment inequity has been furthered by across-the-board cuts to providers caused by sequestration and Congress' misvalued code initiative. According to the Medicare Payment Advisory Commission, in 2016 outpatient payments rose because of rapid growth in Part B drug spending and an increase in physician services billed as hospital outpatient services (which in part reflects hospitals' acquisition of physician practices). We believe the Administration should instead consider the drivers of provider consolidation and support policies that support payment adequacy by site of service.

Conclusion

As described above, physicians face a number of administrative hurdles in obtaining Part D drugs for Medicare beneficiaries, as well as therapies for their privately insured patients. Instead of instituting new hurdles in the way Medicare patients obtain their medications, we ask the

Administration to focus on reducing the administrative challenges that physicians now face. ASGE physician leaders have been pleased to participate in the Acumen-led process of developing episodes of care, and we look forward to continuing to work with CMS to create value-based systems that encourage appropriate use of health care resources, including the use and selection of pharmacologic and biologic therapies. Should you have any questions or require additional information, please contact Lakitia Mayo, ASGE Senior Director, Health Policy and Education, at lmayo@asge.org or (630) 570-5641.

Sincerely,

Steven A. Edmundowicz, MD, FASGE
President