CONSUMER ACTION for a STRONG ECONOMY

June 10, 2025

CASE RESPONSES TO CMS.GOV RFI – "UNLEASHING PROSPERITY THROUGH DEREGULATION OF THE MEDICARE PROGRAM" (EXECUTIVE ORDER 14192)

Unleashing Prosperity Through Deregulation of the Medicare Program (Executive Order 14192)- Request for Information

1A. Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?

The Inflation Reduction Act (IRA) Medicare Drug Price Negotiation Program is a prime example of an unnecessary policy. This "negotiation" program is nothing more than a price control on prescription medications. Like all examples of government price setting, this intervention in the free market will have disastrous downstream effects on our nation's entire innovation ecosystem. Knowledge that they will be able to generate a return on their investment is what allows innovators to safely invest the necessary time and funding into creating new medications. The CMS price controls will slash this incentive by removing the ability to generate revenue. CMS should find ways to pause this program or mitigate its negative effects on our innovation pipeline.

The Coverage with Evidence Development (CED) program is another primary example of overly burdensome regulation. Administered by the CMS, the program provides contingent coverage for select medical treatments dependent upon participation in approved clinical studies. While it intends to support the development of innovative drugs, the program imposes multiple layers of regulatory complexity that hinder access to care. These requirements are not only excessive but also exclusionary, particularly for patients in rural areas who lack access to FDA-approved trial sites. Additionally, the administrative demands, including repeated documentation and coordination with designated physicians, create substantial barriers to care. Rather than expanding access, the program restricts it.

1B. Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

Medicare can also contain a host of complex reporting requirements that create significant obstacles to care. These include prior authorizations from doctors, compliance reporting for both patients and providers and annual reviews of authorizations, each adding to the bureaucratic burden that wastes time and taxpayer money. These could be simplified or eliminated entirely to ease the unnecessary procedural tasks.

1C. Are there specific Medicare administrative processes, quality, or data reporting requirements, that could be automated or simplified to reduce the administrative burden on facilities and other providers?

Prior authorizations from doctors, compliance reporting for both patients and providers, and annual reviews of authorizations should be done away with to cut through red tape. Overly stringent, burdensome requirements strain resources and shift the focus from actual care. As free-market advocates, we take issue with the inefficiency and waste within Medicare health plans. They impose unnecessary regulatory hurdles while wasting taxpayer dollars that fund Medicare—dollars that could be spent on effective patient care.

2A. What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

Eliminating prior authorization within Medicare or streamlining the repeal process will greatly alleviate administrative burdens associated with the program. Taxpayer dollars should go toward patient care, not paperwork.

Moreover, eliminating regulatory burdens within reporting processes writ large will improve program integrity by re-allocating healthcare workers' time.

2B. Are there opportunities to reduce the frequency or complexity of reporting for Medicare providers?

- N/A

2C. Are there documentation or reporting requirements within the Medicare program that are overly complex or redundant? If so, which ones? Please provide the specific Office of Management and Budget (OMB) Control Number or CMS form number. (Note: The OMB Control Number consists of two groups of four digits joined by a hyphen and it generally appears on the top right of the first page of a Medicare form and the CMS form number generally appears on the bottom left of the page of a Medicare form.)

- N/A

3A. Which specific Medicare requirements or processes do you consider duplicative, either within the program itself or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?

CED is unnecessarily duplicative as it adds additional approval processes to drugs already proven safe and effective. Requiring patients to participate in trials for FDA-approved drugs inhibits patient care and wastes government resources.

3B. How can cross-agency collaboration be enhanced to reduce duplicative efforts in auditing, reporting, or compliance monitoring?

CMS should work closely with the Department of Government Efficiency (DOGE) to dramatically reduce regulatory burdens. By cutting through the red tape within the program, DOGE and CMS can improve patient care and save time and resources.

3C. How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

- N/A

4A. We welcome any other suggestions or recommendations for deregulating or reducing the administrative burden on healthcare providers and suppliers that participate in the Medicare program.

We support eliminating superfluous regulatory burdens that impede the free market and hurt taxpaying American patients. Several CMS programs like price "negotiations," CED, and prior authorization delay timely access to innovative treatments and create unnecessary bureaucratic red tape. To truly protect patients, the free market, and our thriving pharmaceutical industry, we must eliminate these government-imposed, wasteful obstacles to care.

There are several other practices, rules, and directives related to the administration, distribution, and budgeting of CMS programs we believe should be modified, updated, or eliminated to not only improve care to patients but relieve unnecessary burdens placed on providers and taxpayers. These include:

- Site Neutral Reimbursement – Currently Medicare pays much higher rates of compensation for services performed in hospitals compared to the same services provided in a physician's facility or in an ambulatory surgical center (ASC). Adopting a site-neutral policy of reimbursement for a procedure regardless of where it is performed could save up to $220 billion per year according to several recent studies from top policy analysts, including Paragon Health Group, MedPac, Leavitt-Partners, and Cassidy-Hassan. All encouraged reimbursement frameworks that eliminate pay disparities between treatment facilities by lowering existing rates and avoiding overly complex incentive structures that may limit participation. The current disparity can be attributed to a long-held assumption among stakeholders in the field of healthcare that hospitals deliver the best care, an assumption that should be evaluated thoroughly by CMS.

- 340B Reform – It is no secret that hospitals are reaping a windfall through the 340B Drug Pricing Program intended to help low-income patients, but which instead has been tragically exploited by large hospitals for financial gain. Medicare Part B currently pays hospitals the full average sales price (ASP) for these drugs, regardless of whether the drugs were acquired at a discount. The Trump Administration reduced Part B payments to 77.5 percent of ASP in 2017 but the rule was struck down by the Supreme Court for technical reasons. CMS should review options that will allow them to cut excessive payments to hospitals which the courts will uphold.

- Uncompensated Care Reimbursement – Similar to the 340B prescription drug program for low-income patients, hospitals are increasingly being called-out for exploiting Medicare reimbursements for charitable assistance and patient non-payment, i.e., "bad debt" for services unrelated to Medicare. More and more, hospitals are making claims for reimbursement to CMS without having shown that they have met program requirements, delivering a healthy boost to their profits at taxpayer expense. Some policymakers are advocating for an end to blanket CMS reimbursements for non-payment and basing reimbursement instead on an individual hospital's share of charitable care actually providing and ending reimbursements for bad debt hospitals carry outside of Medicare. This would not only ensure reimbursements are going to charitable providers for care actually delivered but create greater incentives for hospitals to provide

charitable care to vulnerable patients. One CBO estimate notes this could save $141.7 billion over ten years.

- Chained CPI – Medicare payments are currently tied to the Consumer Price Index (CPI), which measures the costs of goods and services across the entire economy. The CPI, however, does not take into account price elasticity of goods and services, i.e., the effect on consumer behavior with regard to price variations. A more accurate measure of inflationary impact is achieved through chained CPI, as it accounts for consumers adjusting spending or shifting to alternative goods and services due to inflation, which further influences consumer prices. By adopting the more accurate chained CPI it is estimated that CMS could save $27.5 billion over 10 years.

- Medicare Advantage – Medicare Advantage (MA), the program that permits seniors to supplement their basic Medicare fee-for-service (FFS) benefits with a plan that provides wider coverage, continues to grow in popularity. There are an estimated 33 million seniors currently enrolled in MA, or 54 percent of all eligible Medicare beneficiaries. Seniors with the means to adopt such plans generally receive higher quality care and more choices, which has the added benefit of reducing stress on the traditional Medicare program on which other seniors rely. Unfortunately, a thicket of unnecessary and onerous regulations have provoked more and more providers to cease accepting MA. A large portion of this is attributable to increased administrative costs such as pre-approval requirements. Reforms such as capping MA benchmarks to keep cost increases more in-line with FFS Medicare, and creating parity between FFS and MA rules, patient policies, and insurance such as with Medigap, along with a handful of similar MA and FFS alignment policies, could save $250 billion over 10 years.