





May 12, 2025

Honorable Robert F. Kennedy Jr. Secretary U.S. Department of Health and Human Services 200 Independence Ave. SW Washington, DC 20001 Honorable Russell T. Vought Director Office of Management and Budget 725 17th Street NW Washington, DC 20503

Honorable Dr. Mehmet Oz Administrator Centers for Medicare & Medicaid Services 7500 Security Boulevard Baltimore, Maryland 21244-1850

RE: Request for Information: Deregulation (FR Doc. 2025-06316)

Dear Secretary Kennedy, Administrator Oz and Secretary Vought:

On behalf of the hospitals and health system in New York's Hudson Valley and Long Island regions, I thank you for the opportunity to comment on the Office of Management and Budget's (OMB) request for information (RFI) on deregulation.

Health care is one of the most heavily regulated parts of the U.S. economy. While we understand and support thoughtful regulation that protects patients and promotes high-quality and accessible care, recent studies have found that providers spend increasing time on paperwork, not patients. Excessive regulation and administrative burden also limit advancements in medicine, taking time away from providers interested in new research and innovative treatments while simultaneously hampering the ability of hospitals, health systems, post-acute care providers and other health care providers to be more efficient and improve the patient experience. The growing number of regulations also increases costs, driving up the price of health care for everyone. **Therefore, we strongly support your focus on deregulation.**The experience of our member hospitals and health systems reflects this. Duplicative and overlapping surveys, collection of data and reporting on topped-out quality measures, the inability to coordinate effectively with partner providers and modernize models of care, and lack of standardization requirements for health plans all add significant administrative burden and cost. These stresses also compound the ongoing healthcare workforce shortage, with clinicians and allied support staff devoting time to administrative tasks that could be better directed to patient care.

As you consider ways to mitigate regulatory and administrative challenges in the health care system, we encourage you to focus on the following four priority areas. While we provide examples of specific actions the administration could take for each, we welcome additional opportunities to discuss a more comprehensive list.

Billing, Payment and Other Administrative Requirements

Research estimates that between 25-30 percent of all health care spending goes toward administrative tasks, not patient care. These tasks include verifying patients' insurance and coverage status, conducting prior authorizations, and acquiring and managing the personnel and technology to comply with different payment models and payer requirements. To reduce billing and payment-related burden, we recommend the following.

Make all Center for Medicare and Medicaid (CMMI) models voluntary, specifically the Transforming Episode Accountability Model (TEAM) (42 CFR 512.5), and repeal the mandatory Increasing Organ Transplant Access (IOTA) Model (42 CFR 512.412) and the Inpatient Rehabilitation Facility (IRF) Review Choice Demonstration. While we strongly support innovation to improve the quality and accessibility of health care at lower costs, some of the CMMI models as designed could have an immediate detrimental impact on the quality of care or on patients' access to care by overburdening their providers.

The IOTA Model is a complex mandatory payment model that purports to test whether hospital performance-based incentive payments will increase access to kidney transplants; however, these payments are designed to incentivize volume, not quality and, in doing so, could lead to lower quality transplants and thus higher risk of failure.

The TEAM would mandate that more than 740 acute care hospitals receive bundled payments for five types of surgical episodes, irrespective of whether the hospitals are able to implement the bundles and whether they will improve patient care. The model particularly targets hospitals with low levels of existing experience with alternative payment models, increasing the risk that participating in such a model could financially destabilize them, threatening access to care for everyone in the community.

Finally, under the IRF Review Choice Demonstration, IRFs will have 100 percent of their Traditional Medicare claims subject to unnecessary and onerous pre- or post-claim review for at least six months. This will add considerable staffing costs to providers who are already struggling under rising input costs and unstable revenue.

Repeal the excessive, confusing and imbalanced provider disincentives included in the June 2024 final rule "21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking" (RIN 0955-AA05). Under the final rule, hospitals and providers found to engage in information blocking may face reductions in Medicare payment updates, adjustments to reimbursement rates, lower performance scores, and potential ineligibility for certain incentive programs. We believe in the importance of making critical health information available to patients, the clinicians treating those patients, and those with appropriate reasons for having access, among which are payment, care oversight and research. However, the disincentive structure in this rule is excessive, so much so that it may threaten the financial viability of economically fragile hospitals, including many small and rural hospitals. In addition, the processes by which the Office of the Inspector General will determine if information blocking has occurred are unclear, including the appeals process, giving this proposed rule the appearance of being arbitrary and capricious.

Standardize more insurance-related administrative transactions, starting with operationalizing the Interoperability and Prior Authorization Final Rule (CMS-0057-F) to establish standard electronic prior authorization processes in Medicare Advantage, the Health Insurance Marketplaces, and

Medicaid. Hospitals often have hundreds, if not thousands, of contracts with different insurance plans. Each of these plans includes different rules and processes, including the way to communicate requests and share associated documentation with plans (e.g. phone, fax, proprietary portal), the services that are subject to prior authorization, and the clinical criteria a plan will use to adjudicate prior authorization and coverage requests, among other things. There is a tremendous opportunity to streamline many of these rules and processes to both improve patients' access to care while also reducing the costs and burden on providers associated with compliance. For example, prior authorization is frequently applied inappropriately in ways that delay care and harm patients. CMS has taken significant steps to move many health plans towards standardized electronic prior authorization processes. These rules are intended to go into effect in 2026 and 2027, and we urge the administration to ensure robust and timely implementation.

Quality and Patient Safety

High quality, safe care is the core of hospitals' missions. While many regulations originated out of an interest to improve care quality or patient safety, those same regulations, over time, have often become obsolete or redundant. Hospitals and health systems spend billions of dollars annually just on collecting and submitting quality measures, with one survey estimating annual per hospital costs of \$3.5 to \$12 million. The physicians with whom hospitals partner in delivering high-quality care face similarly daunting costs, with physicians in just four specialties — general internal medicine, family medicine, cardiology and orthopedics — spending an estimated \$15.4 billion annually on quality measurement. To reduce burdens related to quality measurement and reporting, we recommend the following.

Repeal outdated COVID-19 reporting mandates including 86 FR 42489, 86 FR 45446, 86 FR 42396, 88 FR 51009, 88 FR 53233, 88 FR 59250, 88 FR 77767 (for post-acute care patients/residents and staff), 86 FR 45382 (for hospital staff), and 42 CFR 482.42(e), 42 CFR 483.90(g), 42 CFR 485.426(e) and 42 CFR 485.640(d) (for hospitals and skilled nursing facilities to report data on acute respiratory illnesses, including influenza, COVID-19 and RSV, once per week, with more frequent and extensive data reporting required during a public health emergency). As noted above, data reporting is an incredibly time intensive activity that pulls clinicians away from patients and costs a considerable amount in both staff time and technology to complete. While we are deeply committed to ensuring the highest quality care — which requires evaluating performance and acting on the findings — it is imperative that we direct our limited resources to the highest impact areas. Unfortunately, hospitals are subject to significant outdated reporting requirements, in particular with respect to the COVID-19 public health emergency. Eliminating this unnecessary reporting would reduce costs in the health care system and enable providers to spend more time with their patients.

Replace the sepsis bundle measure, as required at 79 FR 50241 and 88 FR 59801, with a measure of sepsis outcomes. Hospitals have spent considerable effort — and achieved significant results — in mitigating the incidence and severity of sepsis, saving lives in the process. Unfortunately, research has demonstrated that the sepsis bundle measure has not led to better outcomes yet entails enormous administrative burden. We encourage the administration to work with hospitals on a measure that will help them further advance the fight against sepsis, while reducing unnecessary burdens in the system.

Eliminate duplicative "look back" validation surveys of accrediting organizations (AOs) at 42 CFR 488.9 and permanently adopt concurrent validation surveys. As part of its oversight process, CMS conducts a full re-survey of hospital compliance with Medicare Conditions of Participation on a representative sample of hospitals each year, comparing each hospital's results with the most recent accreditation surveys. Instead of fulfilling CMS' goal of assessing AO performance, the validation

surveys result in rework and disruption for hospitals and health systems. CMS should instead permanently adopt concurrent validation surveys that would allow the agency to directly observe AO performance.

Resume conducting low-risk complaint surveys virtually. During the COVID-19 pandemic, CMS adopted a policy in which accrediting organizations and state survey agencies could conduct complaint surveys of low-risk quality issues virtually. Since then, CMS has instructed AOs to conduct most complaint surveys in person, regardless of severity, and hospitals incur costs for each AO visit. Virtual surveys for low-risk complaints would enable more efficient use of survey resources and reduce administrative costs.

Facilitate whole person care by eliminating 42 CFR Part 2 requirements that hinder care team access to important health information and protect patient privacy under the Health Insurance Portability and Accountability Act of 1996 (HIPAA). Despite regulatory changes in the past several years, the regulations in Part 2 are outdated, fail to protect patient privacy and erect sometimes insurmountable barriers to providing coordinated, whole-person care to people with a history of substance use disorder (SUD). Specifically, the regulations require the separation of records pertaining to SUD information, which prevents the integration of behavioral and physical health care because the patient data cannot be used and disclosed like all other health care data.

Telehealth

As technology and consumer preferences have evolved, more care can safely be delivered via telehealth. However, numerous regulations restrict the use of virtual care, impeding innovation and our ability to deliver care more efficiently. While there are numerous ways to expand access to care using telehealth, we recommend starting with the following.

Remove telehealth originating site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(ii)(X) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(3) to enable patients to receive telehealth in their homes. Under current rules, patients must be in a clinical site of care, which completely undermines the value of telehealth for patients, limits its adoption and adds costs for providers.

Remove telehealth geographic site restrictions within the Medicare program at Sec. 1834(m)(4)(C)(i) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(4) to enable beneficiaries in non-rural areas to have the same access to virtual care as those in rural areas.

Remove the in-person visit requirements for behavioral health telehealth at Sec. 1834(m)(7) of the Social Security Act (42 U.S.C. 1395m) and 42 CFR 410.78(b)(3)(xiv), which is unnecessary, adds a barrier to access, and creates a disparity between physical and mental health services.

Remove requirements at Sec. 3132 of the Affordable Care Act (42 U.S.C. 18001 et. seq.) and 42 CFR 418.22(4) that require hospice recertification to be completed in person to allow for hospice recertification to be completed via telehealth. This change would alleviate the burden on patients and their caregivers, as well as on clinicians.

Workforce

The health care system's greatest asset is its workforce. Unfortunately, doctors, nurses, technicians and others increasingly are burnt out and leaving the profession, often citing excessive administrative burden that pulls them away from patient care. We recommend the following.

Streamline care plan documentation requirements at 42 CFR 483.23(b)(4). To provide higher quality, more holistic care, patients are increasingly cared for by interdisciplinary teams. These teams may include a range of clinical professionals, such as nurses, therapists and social workers. When used, these teams develop what is known as an interdisciplinary care plan. Yet, outdated regulations require nursing-specific care plans. Hence, as more care moves to interdisciplinary teams, clinicians must create duplicate paperwork to document the care plan.

Eliminate the telehealth physician home address reporting requirement, which is currently under waiver as referenced at 89 FR 97110. Without continued waivers or removal, telehealth providers must list their home address on publicly available enrollment and claims forms when performing telehealth services from their homes, compromising their privacy and safety.

Eliminate nurse practitioner and other advanced practice practitioner (APP) limitations at 42 CFR 485.604(a)(2), 42 CFR 485.604(b)(1)-(3), and 42 CFR 485.604(c)(1)-(3). These regulations impose limits on the scope of care APPs may provide that are often more restrictive than under state licensure, despite states having primary responsibility for clinical scope of practice rules. In these cases, hospitals and health systems are constrained in their ability to increase patient access to care through the greater use of APPs.

Remove requirements at 42 CFR 410.61 that require outpatient physical therapy plans of care to be signed off by a physician or non-physician practitioner every 90 days. While CMS made an exception to the treatment plan signature requirement in the calendar year 2025 Physician Fee Schedule for initial care plans where there is a signed referral, the requirement for physicians to sign and date plans of care every 90 days creates an additional administrative burden.

The changes above would go a long way to ease the administrative burden on hospitals, enhancing our ability to provide the highest quality care most efficiently. We appreciate your consideration of these comments.

Sincerely.

Wendy D. Darwell

Is Wendy D. Darwell

President and Chief Executive Officer