Trinity Health

May 8, 2025

Russell T. Vought
Executive Office of the President
Office of Management and Budget
725 17th Street, NW
Washington, DC 20503

Re: Request for Information: Deregulation

Submitted electronically via http://www.regulations.gov

Dear Secretary Vought,

Trinity Health appreciates the opportunity to comment on deregulation. Our comments and recommendations reflect a strong interest in public policies that support better health, better care and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 127,000 colleagues and more than 29,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 93 hospitals, 107 continuing care locations, the second largest PACE program in the country, 142 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 8,200 medical group physicians and providers. Based in Livonia, Michigan, its annual operating revenue is $23.9 billion with $1.3 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 12 Clinically Integrated Networks (CINs) that are accountable for 2 million lives across the country through alternative payment models. Our health care system participates in 12 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 10 markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participated in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). Two of the 12 markets also participate in the Comprehensive Primary Care Plus Model. In addition, we participated for many years in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative and the Comprehensive Care for Joint Replacement (CJR) program across 37 hospitals. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

In addition, Trinity Health owns a non-profit, mission-focused Medicare Advantage plan—MediGold—that plays a vital role in our integrated delivery network and provides care coordination for patients while using fair practices. Serving 56,000 beneficiaries across 6 states, MediGold is a highly-effective best practice plan model. In order to place a better emphasis on care and outcomes rather than profit, MediGold has a lower profit margin and lower administrative costs compared to commercial for-profit plans because they say “yes” more to providers and beneficiaries. In addition, MediGold utilizes standard and transparent guidelines for decisions on precertification and other authorization approval processes, removing ambiguity of guidelines for providers.

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.[1] 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.[2] The growing number of regulations also increases costs, driving up the price of health care for everyone.[3] **Therefore, we strongly support your focus on deregulation.**

As you consider ways to mitigate regulatory and administrative challenges in the health care system, we encourage you to focus on the following recommendations that focus on:

- Reducing administrative waste in billing and payment requirements;
- Simplifying quality and reporting, including by aligning the mandatory measure sets for the Medicare and Medicaid populations where applicable;
- Standardizing flexibilities for telehealth; and
- Reducing the burden on the health care workforce.

**BILLING, PAYMENT AND OTHER ADMINISTRATIVE REQUIREMENTS**

Research estimates that between 25-30% of all health care spending goes toward administrative tasks, not patient care.[4] 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. For example:

- Administrative burden associated with commercial plan denials costs Trinity Health $120 million each year
- Clinical denials require an arduous appeal process with success 55%-66% of the time; yet creates unnecessary burden and leads to administrative waste and physician burn out.

**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

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[1] John Noseworthy, *The Future of Care—Preserving the Patient-Physician Relationship*, NEW ENGL. J. MED. (Dec. 4, 2019), https://www.nejm.org/doi/full/10.1056/NEJMsr1912662; THE PHYSICIANS FOUND., *Viewpoints: Regulatory Burdens* (Jan. 2020), http://physiciansfoundation.org/wp-content/uploads/2020/01/PF-Issue-Brief-Regulatory-Burdens-final.pdf; LaPointe, Jacqueline, *Regulatory Burdens in Healthcare Take Away from Patient Care* (Nov. 15, 2023), https://www.techtarget.com/revcyclemanagement/news/366600273 /Regulatory-Burdens-in-Healthcare-Take-Away-from-Patient-Care.

[2] Christopher James Vincent, et al., *Can Standards and Regulation Keep Up with Health Technology?*, 3(2) J. MED. INTERNET RSCH. 64 (Mar. 6, 2015), https://pmc.ncbi.nlm.nih.gov/articles/PMC4526895/; THE PHYSICIANS FOUND., *Viewpoints: Regulatory Burdens* (Jan. 2020), http://physiciansfoundation.org/wp-content/uploads/2020/01/PF-Issue-Brief-Regulatory-Burdens-final.pdf; Nicol Turner Lee, et al., *Removing Regulatory Barriers to Telehealth Before and After COVID-19* (May 2020), BROOKINGS INST., https://www.brookings.edu/articles/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/.

[3] American Hospital Association, *Regulatory Overload Report: Assessing the Regulatory Burden on Health Systems, Hospitals, and Post-Acute Care Providers* (Oct. 2017), https://www.aha.org/sites/default/files/regulatory-overload-report.pdf; Nicol Turner Lee, et al., *Removing Regulatory Barriers to Telehealth Before and After COVID-19* (May 2020), Brookings Inst., https://www.brookings.edu/articles/removing-regulatory-barriers-to-telehealth-before-and-after-covid-19/.

[4] https://www.healthaffairs.org/content/forefront/administrative-spending-contributes-excess-us-health-spending

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.

In addition, we recommend the following regulatory actions for Medicare Advantage:

**Repeal 42 CFR §422.101(b)(6).** This would remove the ability of MA plans to create their own internal coverage criteria, e.g., for inpatient admissions**.**

**Clarify that the requirements at 42 CFR §412.3 alone, as made effective to Medicare Advantage plans at 42 CFR §422.101(b), fully establishes the applicable coverage criteria for inpatient admissions.** This would help address the continued inpatient denials and downgrades by MA plans and the unnecessary administrative costs and delays associated with those practices inconstant with fee-for-service Medicare.

**Require Medicare Advantage Payers to follow CMS guidelines rather than their own payer policy.** Medicare denies 2-3% of claims where MA payers deny up to 10% of claims, causing unnecessary costs to Providers. We are successful with 85% of all denied dollars– this creates undo burden on our teams and unnecessary cost to recoup denied that could be paid upon initial claim submission by the payers. See Medicare Advantage 42 CFR §422.101(b)(6) for reference.

**Require—and enforce—that Medicare Advantage payers follow the CMS Two Midnight Rule which requires MA payers to pay for Inpatient stays if the Patient stay exceeds two days as of Jan 2024.** Payers continue to acquiesce to their own payer guidelines and do not use this criteria – we have $24.1M in net impact on outstanding claims since Jan 2024. See Medicare Advantage: Repeal 42 CFR §422.101(b)(6) for reference.

**Require insurance payers to address claims in a timely manner.** While Hospitals are held to a strict standard, payers hold claims for 2-3 months, specifically any claims that require manual review (ie Review for Clinical Appeals submitted by the hospital, Review of Medical Record Documentations, etc.). This causes excess work efforts for providers and then manual administrative burden to bring these claims forward to resolve during routine payer meetings. For example, in 2024, we escalated more than $100M to payers with the majority of claims being paid by the payer.

**Simplify the definition of emergency services at 42 CFR §422.113 by adding the following text at a new section 42 CFR §422.113(b)((ii)(C) "furnished after the participant, beneficiary, or enrollee is stabilized and as part of outpatient observation or an inpatient or outpatient stay" and adding an "or" at the end of sentence at section 42 CFR §422.113(b)(ii)(B).** This would prohibit MA plans from requiring prior authorization for post-stabilization services by including post-stabilization in the definition of emergency services (similar to the NSA's definition).

**Medicare Traditional (Parts A & B) and Medicare Advantage (MA) (Part C) should be consistent, adhering to the same regulatory and payment framework.** One example of where this could have avoided potential payment challenges is if the MA plans had followed the Medicare Pricer, when OPPS was increased due to budget neutrality of ASP-22% payment adjustments, then when reversed the budget neutrality adjustments for the next 16 years starting 1/1/26 reduce the Medicare Pricer, hospitals and MA plans will have to be vigilant and work together to ensure that MA plans do not unjustly reduce their payments in instances where they never raised their payments in the earlier years.

Trinity Health strongly supports protecting patients from unexpected medical bills and the goals of surprise billing. We recommend the following changes to reduce burdens on providers and ensure insurers pay for services:

- **Revert the independent dispute resolution process administrative fee (at 45 CFR §149.510(d)(2)) and associated regulations) to $50.**

- **Implement the October 27, 2023, proposed rule, with the exception of the 25 item/service limitation for single patient encounters that are considered batched disputes under the proposed rule.** Implementation of the proposed rule would, in part, address some of the IDR timeliness issues.

- **Impose penalties on those parties that do not remit payment for the offer selected by an Independent Dispute Resolution Entity within the timeframes set at 45 CFR §149.510(c)(4)(ix).**

- **Require Independent Dispute Resolution Entities to return or forego the Certified IDR Entity Fee provided under 45 CFR §149.510(d(1) if the Independent Dispute Resolution Entity does not issue a determination within the timeframes required at 45 CFR §149.510(c)(4)(ii).**

- **Repeal 45 CFR §149.110(b)(5)(i) (and associated regulations) as these regulations allow payers to deny coverage for emergency services for coordination of benefit reasons**, which occur when multiple insurance plans are involved in covering a patient's healthcare costs and there is confusion or lack of clarity about which plan is primary and which is secondary.

- **Repeal 45 CFR §149.610(b)(v), which requires that a convening provider include a co-provider or co-facility's good faith estimate (GFE) in the convening provider's GFE.**

- **Continue enforcement discretion for PHS 2799B–6(2)(a) indefinitely.** This is the advanced explanation of benefits (AEOB) GFE requirements that have not yet gone into effect.

**MEDICARE BAD DEBT POLICY**

**Eliminate the "must bill" policy for dual-eligible beneficiaries.** The Medicare Act permits the State Medicaid agencies to limit payment for Medicare cost-sharing to the amount necessary to provide a total payment to the provider equal to the amount a State would have paid for the service under the Medicaid State plan, referred to as the "lesser of" policy. The "must-bill" policy requires for dual eligible beneficiaries that the Provider bill Medicaid to determine whether the State's Medicaid program is responsible for paying all or a portion of the beneficiary's Medicare deductible

and/or coinsurance. Medicaid in most circumstances will not have a liability in these instances, so the "must bill" policy results in unnecessary, costly efforts by the hospitals to submit claims to the State Medicaid agencies when no payment is expected. At time of audit, the hospital must produce a zero-payment Medicaid remittance to the auditor as proof that Medicaid was billed for the coinsurance and deductible.

**MEDICARE ADMINISTRATIVE CONTRACTORS (MACs)**

**Hospitals should be able to change MACs so that a health system can have a common MAC**. This used to be allowed, but was revoked and the ability for a hospital to change MACs was eliminated. There are instances, due to health system mergers, sale, acquisitions, where hospitals may have a legacy MAC that is not the approved MAC for the jurisdiction that the hospital is located. For example, Trinity Health has two hospitals in the same state with two different MACs. One has the jurisdictional MAC and the other has a legacy MAC from when a prior health system parent had taken advantage of the opportunity to have one national MAC. These two hospitals in one state, with a shared billing office, have to deal with differing MAC policies, procedures, local coverage determinations, etc.

**MACs should be required to operate consistently.** Handling of issues that are common across regions related to audit or claims should be coordinated and handled consistently by MACs, as many hospitals are members of multi-state health systems. Inefficiencies and additional costs can occur within the health system when MACs are not consistent.

**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.[5,6] 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.[7] 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.

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[6] "Observations from the field: Reporting Quality Metrics in Health Care." Dunlap NE et al. National Academies Press; 2016. https://nam.edu/wp-content/uploads/2016/07/Observations-from-the-Field-Reporting-Quality-Metrics-in-Health-Care.pdf

[7] "US Physician Practices Spend More Than $15.4 Billion Annually To Report Quality Measures." Casalino LM et al. Health Affairs. Volume 35, Number 3. March 2016.

**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.

**We urge CMS to align the mandatory measure sets for the Medicare and Medicaid populations**, where it makes sense, as outlined in the NEJM article, Aligning Quality Measures across CMS—The Universal Foundation. In addition, CMS should align patient experience survey questions across Medicaid and Medicare. Currently, there is variation in mandatory MIPS CAHPS survey questions from the standard set of questions proposed for the Medicaid population. Finally, CMS should consider adopting standard core measure sets that include both primary and specialty care such as the National Quality Foundation CQMC metrics: NQF: CQMC Core Sets (qualityforum.org)

In addition, we recommend the following changes to Medicare quality reporting requirements:

- Inpatient Quality Reporting
    - **THA/TKA PROM measure – remove 50% performance threshold**. Maintain this as a mandatory measure with no performance threshold for at least 2 years. Patient responses for 1-year post surgery are very low and incomplete. Performance threshold is not attainable for first years of reporting.
    - IQR and PI stepwise increase in eCQM reporting requires significant build and validation work. **We recommend delaying the CY2026 increased reporting requirements.**

- Outpatient Quality Reporting
    - OQR Mandatory Excessive Radiation Dose measure requires a third-party vendor to complete calculations. The complexity of this implementation is significant. **Trinity Health recommends CMS change to voluntary reporting for at least two years to allow for third-party/calculation issues to be resolved.**
    - **OQR voluntary measure for Cataracts needs to remain voluntary.** CMS periodically considers making this mandatory; however, obtaining survey data from provider offices is extremely burdensome to hospitals.

- ACO Electronic Reporting
    - **The mandatory transition to ACO electronic quality reporting is burdensome; we advocate for the extension of ACO web interface reporting with the option of eCQM dual reporting to allow us time to partner with EHR vendors and care teams to ensure technical capabilities and workflows are in place to accurately represent our quality performance**. It would be most helpful if the web interface remained an option until CMS and EHR vendors formalize the dQM reporting methodology so we only have to transition to a new reporting format once.

**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**

Trinity Health's greatest asset is our 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.

## CONCLUSION

The changes above would go a long way to ease the administrative burden on Trinity Health, enhancing our ability to provide the highest quality care most efficiently and reducing waste in our nation's health care system. We appreciate your consideration of these comments. If you have any questions on our comments, please feel free to contact me at jennifer.nading@trinity-health.org.

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health