Trinity Health

June 9, 2025

Dr. Mehmet Oz, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1829-P; Medicare Program; Inpatient Rehabilitation Facility Prospective Payment System for Federal Fiscal Year 2026 and Updates to the IRF Quality Reporting Program

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

Dear Administrator Oz,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1829-P. 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. In addition, the comments below are recommendations on modifications to the Medicare fee-for-service payment system. Many of these issues would be lessened, or in some cases eliminated, if CMS gave non-profit health systems, such as Trinity Health, more accountability in total cost of care payment and delivery arrangements.

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 (a total cost of care program), 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.

In our detailed comments below, we urge CMS to:

- Provide a fair and appropriate payment update to IRFs;
- Finalize proposed changes to the IRF quality reporting program that would reduce burden; and
- Make broader reforms to reduce burden to health care systems

Payment Update

CMS estimates that its proposed rule would increase net payments to IRFs in FY 2026 by 2.8% relative to FY 2025. This includes a 3.4% market basket update offset by a statutorily mandated productivity factor cut of 0.8%. This overall estimate also includes CMS’ estimates that its proposed reduction to the outlier threshold would increase payments by 0.2% in FY2026.

Trinity Health is concerned that CMS’ market basket updates continue to lag behind the increased costs facing hospitals as well as inflation. **We urge CMS to provide a more fair and appropriate payment update that reflects the cost of caring for Medicare patients**. **In MedPAC’s March 2025 IRF Report to Congress, it is noted that nonprofit IRFs have a lower profit margin than for-profit IRFs.[1] We recommend CMS explore these differences and how these tie to quality and outcomes**.

MedPAC has stated in their 2025 report that for the two-year period of 2022 through 2023, “the median facility risk adjusted rate of discharge to the community from IRFs was 67.2 percent, essentially stable from the prior period of 2021 through 2022. The median facility risk-adjusted rate of potentially preventable readmission remained relatively stable at 8.8 percent compared with the rate of 8.6 percent over the period from 2021 through 2022 and was higher for freestanding and for-profit providers then for hospital based and nonprofit facilities.”

MedPAC then goes on to note that free standing IRFs have potentially more barriers due to being free standing, which can lead to higher rates of re-admission as they don’t have access to consults like hospital based IRFs. In future research, we urge CMS and MedPAC to divide free standing IRFs into for and not for profit categories and compare data.

The MedPAC report recommends for FY2026 the IRF base payment should be reduced by 7%. This presumption is based on flawed interpretation of the data. We believe that if the data had been delineated by for-profit and not-for profit, it is possible, and even likely, that it will illustrate that not-for-profits have smaller profit margins because they aren’t beholden to make profits for shareholders and instead reinvest margins into patient care. In addition, examining the FFS Medicare marginal profit may not yield additional information about the adequacy of FFS Medicare payment rates and we suggest looking at QM data would be more accurate along with drilling into for-profit data.

IRF Quality Reporting Program (QRF)

[1] 2025 MEDPAC Report to Congress

Beginning with the reporting period starting Oct. 1, 2025, CMS proposes to make optional the reporting of four standardized patient assessment data elements (SPADE) in the IRF Patient Assessment Instrument (PAI) *focused on social determinants of health (SDOH)*. In addition, CMS proposes to remove two COVID-19 vaccination measures from the IRF QRP for FY 2026 — one focused on patients and the other on health care personnel. CMS also proposes to amend the reconsideration policy and process to remove the word "extenuating" used in previous iterations of the reconsideration policy and replacing it with "extraordinary."

Trinity Health supports the removal of the 2 COVID QRP Measures as it is difficult to measure and define "up to date". **Trinity Health continues to support capturing data on SDOH; however, we agree with the proposed removal of this data at this time because case management captures this information upon initial assessment. For future capture of this data, we urge CMS to assist in translating data captured to add value and actionability to the IRFs and their beneficiaries.**

Trinity Health also supports the change in wording from "extenuating" to "extraordinary" as this aligns with other post-acute care setting language, specifically outpatient departments, and changing this wording would not have an impact on outcome.

Request for Information - QRP

CMS seeks feedback on potential revisions to the IRF-Patient Assessment Instrument (IRF-PAI), which would allow CMS to reduce burden and revisions to the data submission deadlines for assessment data.

Trinity Health welcomes data collection as it drives processes and improvement, and we applaud CMS for seeking ways to reduce burden. **We recommend CMS implement a shorter PAI to reduce burden. In addition, urge CMS to align the PAI with other post-acute care settings and identify ways to make the PAI more age inclusive. If CMS decides to distinguish discharge types in the PAI, the agency should ensure it is designed in a way that does not increase time/burden to complete.**

With regard to potential changes in data submission deadlines for assessment data, **we support moving from 135 days to 45 days as this would allow CMS to provide IRFs with more timely quality data.**

Burden Reduction Request for Information

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.[2] 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.[3] The growing

[2] 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.

[3] 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*

number of regulations also increases costs, driving up the price of health care for everyone.[4] **Therefore, we strongly support the administration's focus on deregulation.**

Trinity Health provides care across the care continuum. 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 and burden on the following areas:

- Billing and payment requirements;
- Quality and reporting; populations where applicable;
- telehealth;
- The health care workforce;
- ACOs and other APMs; and
- Continuing care

BILLING, PAYMENT AND OTHER ADMINISTRATIVE REQUIREMENTS

Research estimates that between 25-30% of all health care spending goes toward administrative tasks, not patient care.[5] 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 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.

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/.

[4] 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/.

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

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.[6,7] 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.[8] 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

[7] "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

[8] "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.

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.

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.

Rescind proposed rule on Special Registrations for Telemedicine and Limited State Telemedicine Registrations. Trinity Health requests the rescission of this proposed rule based on its burdensome nature and the costs imposed on small entities, and for the Administrator of the Drug Enforcement Administration (DEA) and

the Secretary of Health and Human Services to use existing authority, provided them by the Ryan Haight Online Pharmacy Consumer Protection Act of 2008, to jointly provide exemptions to hospice and skilled nursing providers from any future similar rules.

Code: DEA-407: Special Registrations for Telemedicine and Limited State Telemedicine Registrations.

We strongly encourage the DEA to revise these rules, in consultation with stakeholders, to further account for providers who serve equally vulnerable individuals outside of nursing homes and hospices, including providers serving palliative care patients and home health patients.

We fully understand the difficult situation the DEA finds itself in regarding protecting against the abuse of controlled substances while also ensuring Americans can access needed medicine and use telemedicine consultations as a method of access. We also agree that guardrails are needed around telehealth utilization broadly and most especially when there is a high-risk situation such as overprescribing of controlled medications. However, Trinity Health is seriously concerned that the proposed rule laid out by DEA will only further limit access to critical drugs for the vulnerable older adults, especially those at end of life.

We do not believe prescribing controlled medications using telehealth for hospice patients or residents in long-term care is a high-risk situation that requires the guardrails outlined in DEA's proposed rule. Furthermore, the consequences of adding additional oversight to hospice and skilled nursing clinical practitioners, especially with requirements for prescribing schedule II-controlled substances which are critically needed in these settings, would not only be burdensome but would also create catastrophic access issues for the older adults these settings serve. We are most concerned regarding the unduly restrictive nature of the guardrails for schedule II-controlled substances which are commonly found in these care settings.

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.

ACOs AND OTHER APMs

Restoring Prior Benchmark Approaches

CMS should remove the Accountable Care Prospective Trend (ACPT), which has significantly underestimated Medicare cost growth. While the 2024 ACPT estimated Medicare cost growth to be 4.9 percent, actual growth was nearly double (8 percent). This means that the ACPT will artificially and unfairly reduce ACO benchmarks by 1.03 percent, which, for the average ACO, could reduce revenue earned by 25 percent. Significantly underfunding ACOs will force ACOs to reconsider their approaches for managing patients, reducing the burden of chronic illness, and providing patients with services that promote wellness but are not typically covered by Medicare. This policy was put in place to address benchmark ratchets, where ACOs are penalized for their prior success. However, this policy inadequately addresses the benchmark ratchet, lacks transparency, and risks inaccurately updating benchmarks when the prospective trend is incorrect.

Quality Reporting Burden

Focus on progression to digital quality rather than interim steps. An efficient, technology-enabled future where data can be shared bi-directionally to better inform patient care is the future state many in the health care industry want to achieve. Digital measurement should allow for seamless quality reporting that reduces burden and provides real-time performance data that can be used to improve patient care.

CMS's current requirements force ACOs to make investments in infrastructure that will be wasted as ACOs would otherwise be transitioning to the HL7 Fast Healthcare Interoperability Resources (FHIR) standard. The mandatory transition to ACO electronic quality reporting is burdensome and does not move ACOs closer to true digital quality measurement (dQM) that accurately represents quality of care and provides actionable insights for quality improvement. To alleviate these burdens:

- CMS should retain access to all existing ACO reporting options during the transition to dQM, which will require appropriate industry-readiness.
- ACOs should not be required to report on any new measures during the transition to dQM to allow time for electronic health record (EHR) vendors to ensure technical capabilities and workflows are in place.

Several aspects of MSSP quality reporting have been revised to align with the Merit-based Incentive Payment System (MIPS). This is counter to the congressional intent of the Medicare Access and CHIP Reauthorization Act (MACRA), which sought to exempt physicians and other clinicians who meaningfully participate in APMs from burdensome MIPS requirements. **CMS should remove burdensome requirements that were implemented to align with MIPS:**

- *All-patient all-payer reporting.* This requirement inadvertently penalizes ACOs with specialist participants by requiring reporting and assessment of all-payer and all-patient data rather than focusing on ACO assigned patients. As a result, specialists in the ACO are held accountable for primary care measures that are not clinically appropriate. For example, dermatologists in the ACO would be required to assess and do follow-up on depression screenings, which would not be clinically appropriate. Ultimately this

would lead to artificially lowering the ACO's quality score and assessing ACOs based on the case-mix of their population and the proportion of specialists in the ACO.

- *Certified Electronic Health Record Technology (CEHRT) attestation.* Recently, CMS required ACOs and its participants to report MIPS Promoting Interoperability (PI), significantly increasing burden, without any added value, and jeopardizing participation in MSSP, particularly for small practices. CMS should revert to the previous approach using a simplified attestation.

Beneficiary Communications and Engagement

Current regulations in the MSSP hamper ACO providers' ability to effectively communicate with beneficiaries about accountable care. Rigid beneficiary notification requirements add cost and burden to ACO participants and have caused confusion and frustration for Medicare beneficiaries, in direct contrast with the intention of the requirements. Revising duplicative, complex, and burdensome requirements will help foster patient-provider relationships while improving beneficiaries' understanding of accountable care. **To eliminate unnecessary burden and improve patient engagement with ACOs, CMS should:**

- **Eliminate the follow-up communication requirement for beneficiary notifications and vastly simplify overall beneficiary notification requirements to alleviate beneficiary confusion. ACOs know their patients best and should have flexibility in how they communicate with patients.**
- **Create parity between marketing rules for ACOs and Medicare Advantage (MA), which would enable ACOs to create more educational resources for beneficiaries.**
- **Streamline the approach for voluntary alignment to make it a more useful tool for beneficiary engagement and foster patient choice. This should include aligning the MSSP approach with signed voluntary alignment in REACH and allowing ACO providers to discuss voluntary alignment with homebound patients.**

Data and Reporting

Managing populations requires access to data to understand patient health needs and analyze trends in utilization, cost, and quality. More efficient requirements around data exchange and reporting requirements for ACOs would reduce burden and improve integration of care. **CMS should:**

- **Remove current restrictions on substance use disorder (SUD) claims data, which are currently excluded from the Claim and Claim Line Feed (CCLF) files ACOs receive, despite Congress's efforts to align 42 CFR Part 2 with Health Insurance Portability and Accountability Act (HIPAA) through Section 3221 of the Coronavirus Aid, Relief, and Economic Security Act (CARES Act). This creates barriers to providing coordinated, integrated behavioral health care.**
- **Make the full Medicare data set available to all APM participants to facilitate accurate benchmarking and provider evaluation.**
- **Eliminate the ACO public reporting requirement as it is duplicative; instead require ACOs to link to publicly available data from CMS.**
- **Remove the monthly ACO provider reporting requirement, which does not change CMS provider records and offers no benefit while creating unnecessary burden.**

Waivers and Innovation

Waivers offer APM participants unique opportunities to innovate care delivery and create a strong nonfinancial incentive to participate. Waivers available to MSSP ACOs have been limited to-date, hampering potential innovations in the permanent program. Further, arduous documentation and implementation requirements to utilize waivers have hindered their use. **To unlock innovation in Medicare's value models, CMS should:**

- **Implement all Innovation Center waivers in MSSP and allow a process for APM participants to recommend and test new waivers.**
- **Simplify required reporting for waiver implementation and use.**
- **Allow ACOs to select subpopulations for which to implement waivers.**
- **Expand access to primary care capitation in MSSP by simplifying the payment approach from what is in the ACO Primary Care Flex Model and allowing all MSSP ACOs the option to elect primary care capitation and shift the underlying payment mechanism away from fee-for-service.**
- **More closely align APM waivers with MA flexibilities; for example, by waiving the scheduling restriction on Annual Wellness Visits (AWVs) and instead allowing AWVs to be scheduled once per calendar year.**

CONTINUING CARE
Trinity Health serves populations across the care continuum. The following are recommendations for reducing burden that will enable us to better serve our continuing care patients.

Regulation: Program for All-Inclusive Care for the Elderly (PACE) Effective Date of Enrollment
Trinity Health requests that this rule be repealed, and that CMS allow, instead, people to be enrolled into PACE programs upon eligibility rather than the first day of the next month.

Code: 42 CFR 460.158 Effective date of enrollment

This regulation unnecessarily requires the PACE enrollment date to be the first of the month, but the enrollment date could be the date the participant signs the enrollment agreement. CMS could easily determine a way to pay providers on partial month capitation regimens as it does in all other programs. Because someone is only eligible for PACE when they meet the clinical eligibility criteria for a nursing home, limiting PACE enrollment to the first of the month is a barrier to accessing life-saving services.

This outdated rule puts the wellbeing of people with notable physical or cognitive limitations in jeopardy and can cause significant health decline before a PACE program is allowed take the person in on the first of the next month. The rule then translates into unnecessary spending on preventable deterioration because the health risks only worsen when enrollment is delayed. This then contributes to PACE organizations' Risk Adjustments, resulting in higher payments. This offsets the costs to PACE organizations but could have been avoided both by the PACE organization and CMS if the person were able to be admitted at the time they found out about the program and were deemed to be eligible.

Regulation: PACE marketing restrictions
Trinity Health recommends the elimination of provisions that limit the ability of PACE organizations to engage in direct marketing.

Code: 42 CFR 460.82(e)(5) PACE direct marketing

The CMS provision that limits the ability of PACE organizations to engage in direct marketing is strongly worded and can be construed to mean that no unsolicited marketing is allowed. This provision should be completely eliminated.

Other limitations on PACE marketing, including those related to the extent of services, enrollment procedures, and approval by CMS of all materials, are safeguards that ensure that PACE marketing to eligible individuals will not be misleading.

PACE is a program uniquely customized for dual eligibles, but current marketing restrictions prevent PACE organizations from directly promoting their services. This places both PACE programs and dual eligible beneficiaries at a disadvantage when evaluating Medicare options. Unlike Medicare Advantage (MA) and Special Needs Plans, PACE programs are not listed on the Medicare Plan Finder, and Medicare plan brokers often lack sufficient knowledge about how PACE compares to MA-only or Special Needs Plans. As a result, Medicare beneficiaries who could benefit from PACE are not fully informed of all their options, since PACE programs are restricted from direct marketing.

This regulation in its entirety is burdensome in that it unfairly discriminates against PACE programs, when compared with other Medicare Advantage (MA) plans, by placing undue restrictions on PACE marketing practices while not requiring other MA plans to abide by these same restrictions.

Trinity Health also requests the following be considered:

- Service determination requests (SDRs) should be reported quarterly just as appeals and grievances are. Anything that is reported quarterly (part of PACE Quality Data Monitoring & Reporting Guidance, including appeals and grievances) should not have to be submitted by the PO again for an audit since CMS already has all the information in HPMS. This process would reduce the amount of information gathering for audits by the PO and reviewing for CMS auditors as all quarterly information should be reviewed and documented by each CMS rep on a quarterly basis.

- It is recommended to align federal and state reporting requirements to reduce duplication, striving for a multi-agency submission process, as well as alignment of regulatory requirements, for example CMS requirements for assessment completion compared to the state of Maryland are not the same.

Regulation: Minimum Staffing Standards for Long-Term Care Facilities and Medicaid Institutional Payment Transparency Reporting

Trinity Health requests that this rule be eliminated in its entirety.

Code: 42 CFR 483.35(b) and (c)

The Minimum Staffing Standards for Long-Term Care Facilities final rule was published in the Federal Register on May 10, 2024. This rule requires nursing homes to have a registered nurse on-site twenty-four hours per day, seven days per week in every nursing home, regardless of the assessed needs of the unique resident population or the skills and competencies of the existing staff. The rule further requires all nursing homes to provide 3.48 hours per resident, per day or total nurse staffing, including 0.55 hours per resident, per day of registered nurse services and 2.45 hours per resident, per day of nurse aide services. This requirement exceeds the statutory requirement to provide 24-hour licensed nurse services sufficient to meet the needs of residents and to use the services of a registered nurse at least eight consecutive hours per day, seven days per week. Inability to meet staffing standards may cause nursing homes to limit admissions, take beds offline, or close entirely, resulting in barriers to access for older adults seeking skilled nursing or long-term care.

In May 2024, the American Health Care Association filed a lawsuit claiming, among other complaints, that the Centers for Medicare & Medicaid Services (CMS) exceeded statutory authority in issuing these requirements. LeadingAge joined the lawsuit in June 2024 as co-plaintiff. On April 7, Judge Matthew Kacsmaryk of the United States District Court for the Northern District of Texas, Amarillo Division, issued his decision finding that CMS indeed had exceeded statutory authority and vacating the requirements.

The rule would also require Medicaid state agencies to report annually to CMS the amount of nursing home Medicaid payments spent on compensation of the direct care workforce. This reporting by state agencies would require reporting from individual nursing home providers to the state agency in order for the state agency to report the information to CMS. Reporting the amount of Medicaid payments spent on direct staff compensation is an administrative burden that does not meet the intent of the requirement and creates opportunity for inaccurate conclusions to be drawn about Medicaid spending that could negatively and erroneously influence future policies.

Requiring reporting on the percentage of Medicaid payments spent on compensation implies that compensation of direct care and support staff are the only valid uses of Medicaid dollars. In fact, there are many valid expenses outside of direct care staff compensation on which Medicaid payments are spent. Evaluating, testing, and revising emergency plans and updating resident rooms from multiple occupancy to private rooms with improved ventilation are examples of important uses of nursing home funds that would be overlooked with this type of reporting requirement.

Regulation: Respiratory Illness Reporting

Trinity Health requests that this requirement be rescinded as it is unnecessary and duplicative of other federal requirements.

Code: 42 CFR 483.80(g) Infection Control, Respiratory illness reporting.

Under infection control requirements, nursing homes must report information on acute respiratory illnesses, including influenza, severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2), and respiratory syncytial virus (RSV) through a standardized format and frequency specified by the Secretary.

At present, this format and frequency is weekly reporting through the National Healthcare Safety Network (NHSN) system, an online reporting platform that is developed, maintained, and utilized by the Centers for Disease Control & Prevention (CDC). The data currently reported includes facility census, resident vaccination status for the three identified respiratory illnesses, confirmed cases among nursing home residents for each illness, and hospitalizations of nursing home residents for each illness.

Weekly reporting of respiratory illness data was initiated during the COVID-19 public health emergency. At that time, a strong federal response was needed to monitor this catastrophic new virus and coordinate state and federal strategies for preventing and responding to outbreaks. The data was used to learn about this novel virus as well as inform the distribution of supplies and support from the federal government to state and local governments and entities. However, we have learned much in the five years since this virus emerged and the impact of the virus has significantly changed.

We are no longer in a national public health emergency and the federal government is no longer involved in large-scale efforts to provide resources and support coordinated response to long-term care. Allocations of PPE from HHS ended mid-way through the PHE, and strike teams are also a relic of the early days. Similarly, while nursing homes continue to receive support from public health, these responses are local activities, not federal response efforts, and are driven by local conditions within the state or region rather than conditions across the country.

We note that public health entities would continue to have access to data on respiratory illness outbreaks, even without NHSN data, due to separate existing requirements to report outbreaks to public health authorities. Per these requirements, nursing homes would continue to report clusters of respiratory virus symptoms and confirmed cases to public health, allowing for continued situational awareness, support, and outreach.

Regulation: Civil Money Penalties: Basis for Imposing Penalty

Trinity Health requests that this requirement be eliminated, as it imposes undue financial burden on nursing homes.

Code: 42 CFR 488.430 Civil Money Penalties: Basis for Imposing Penalty

Nursing homes are cited for noncompliance with Requirements of Participation through the survey and certification process. As a result of findings of noncompliance, CMS or the state may impose financial penalties on the nursing home in an effort to ensure a return to and maintenance of compliance. Requirements at 42 CFR 488.430 give CMS or the state survey agency the authority to enforce multiple financial penalties for a single type of noncompliance, such as per day and per instance civil money penalties, regardless of whether or not the deficient practice constituted immediate jeopardy.

Allowing CMS or the state to impose multiple penalties on the nursing home for noncompliance creates barriers to quality improvement. When nursing homes are assessed large fines for noncompliance that was promptly corrected, they have less money available for the care and services residents depend on. This means less money is available to recruit and retain staff, implement quality improvement initiatives, or make improvements to the physical environment such as renovating outdated physical structures to improve indoor air quality and accommodate private rooms.

Nursing homes facing extreme financial hardship may even be forced to amend operations including the need to reduce resident programs, reduce staff, reduce admissions, or close entirely, creating access issues for older adults seeking nursing home care.

Eliminating this requirement will lessen the punitive overreach of CMS and state agencies and allow providers more financial flexibility to address areas of noncompliance and needed quality improvement.

Regulation: Resident assessment, Preadmission screening for individuals with a mental disorder and individuals with intellectual disability

Trinity Health requests that this requirement be rescinded as it represents outdated and unnecessary requirements that are unduly burdensome.

Code: 42 CFR 483.20(k) Resident assessment, Preadmission screening for individuals with a mental disorder and individuals with intellectual disability

This requirement was implemented as a result of the 1987 Omnibus Budget Reconciliation Act (OBRA '87) to prevent unnecessary placement of individuals with mental illness or intellectual disabilities in nursing homes. Under these requirements, nursing homes must complete preadmission screening to determine that individuals with mental illness or intellectual disabilities require the level of services provided by the nursing home. These preadmission screenings require the state mental health or intellectual disabilities authority to decide based on an independent physical and mental evaluation performed prior to admission by a person or entity other than the state authority or nursing home. Both the evaluation and the determination by the state authority often require agency coordination that causes unnecessary delays in admission to the nursing home.

While inappropriate placement of individuals with mental illness or intellectual disabilities in nursing homes must still be prevented, requirements for pre-admission screening and referral as operationalized through 42 CFR 483.20(k) are unnecessary due to subsequent requirements implemented through the 2016 Mega Rule, "Requirements for Participation in Medicare and Medicaid Programs" that require resident assessment and care planning for all residents ensure that the needs of residents are identified and addressed, and that nursing homes do not admit residents whose needs they are unable to meet. Requirements at 42 CFR 483.30 require that physicians personally approve, in writing, recommendations for individuals to be admitted to the nursing home.

According to requirements at 42 CFR 483.21(a)(1), nursing homes must assess a resident's needs and develop a baseline care plan within 48 hours of admission. Per requirements at 42 CFR 483.20(b) and 483.21(b), a comprehensive assessment must be completed within 14 days of admission and a comprehensive care plan developed within 7 days of the assessment, and both the assessment and care plan must be reevaluated upon a significant change in functioning or at least quarterly thereafter.

These requirements for assessment and care planning ensure that individuals with mental illness or intellectual disabilities are appropriately placed and that their needs are promptly identified and addressed. Eliminating PASARR requirements at 42 CFR 483.20(k) will lessen administrative burden on both nursing home providers and state agencies while also preventing unnecessary delays in admission for individuals in need of nursing home care.

Regulation: Methodology for Evaluating Home Health Patient-Driven Grouping Model Budget Neutrality

Trinity Health requests the rescission of this methodology as it is not based on the best reading of the underlying statutory authority, and it exceeds the scope of power vested in the agency. Further, CMS should use its authority to prevent the application of additional permanent or temporary payment adjustments to this sector, which has experienced significant reductions in access over the last decade.

Code: 1895(b)(3)(D)(i) of the Social Security Act Methodology for Evaluating Home Health Patient-Driven Grouping Model Budget Neutrality

In the CY2022 Home Health Final Rule, we believe that CMS incorrectly interpreted federal statute. Under Section 1895(b)(3)(D)(i) of the Social Security Act, CMS is required to reconcile payment rates from the patient-driven grouping model (PDGM) to achieve budget neutrality in comparison to the former Home Health

Prospective Payment System (HHPPS) model through 2026. Section 1895(b)(3)(D)(i) states: *The Secretary shall annually determine the impact of differences between assumed behavior changes (as described in paragraph (3)(A)(iv)) and actual behavior changes on estimated aggregate expenditures under this subsection with respect to years beginning with 2020 and ending with 2026*.

CMS' CY2022 finalized methodology for assessing whether actual PDGM aggregate expenditures in 2020 equaled a budget neutral level in relation to the level of expenditures is not limited to a focus on PDGM assumed behavior changes. Those assumed behavior changes were related to the primary diagnosis, LUPA volume, and incidence of comorbidities. However, CMS included considerations of volume of therapy visit changes, contrary to the requirement to eliminate therapy thresholds in 2019. This change in therapy thresholds occurred one year prior to the implementation of PDGM and violates paragraph (3)(A)(iv), which clearly states assumed behavior changes are those "that could occur as a result of the implementation of paragraph (2)(B) and the case-mix adjustment factors established under paragraph (4)(B) …." Paragraph (2)(B) refers to the establishment of a 30-day episode of payment that began in 2020 under PDGM.

CMS must utilize a PDGM budget neutrality methodology that is solely focused on assumed behavior changes that were incorporated into the original 2020 rate setting. The National Association of Home Care and Hospice, now the Alliance for Care in the Home, initiated a lawsuit in July 2023 against the Department of Health and Human Services regarding this incorrect interpretation of statute. The lawsuit was dismissed April 26, 2023, on procedural grounds that administrative remedies had not been exhausted. The inappropriate interpretation of this statute has led to significant reductions in payment to Home Health Agencies (HHAs) over the last three years and has contributed to the decreasing number of HHAs nationally.

Regulation: Staffing Requirements for Home Health Initial and Comprehensive Assessment Visit

Trinity Health believes this regulation must be replaced as it is inconsistent with statutory text, is outdated based on the experiences during the COVID-19 public health emergency which saw no adverse effects to a similar waiver and generally is a burden to home health agencies by not allowing them to utilize their staff to the full scope of their professional abilities.

Code: § 484.55(a)(2) and (b)(3)

At the beginning of the COVID-19 Public Health Emergency (PHE), CMS waived the requirements at § 484.55(a)(2) and (b)(3) permitting rehabilitation professionals to perform the initial and comprehensive assessment in instances when both nursing and therapy services are ordered. This helped alleviate pressures on the nursing workforce during the PHE and allowed rehabilitation professionals to perform the initial and comprehensive assessment for patients receiving therapy services as part of the broader nursing and therapy care plan, to the extent permitted under State law, regardless of whether the therapy service established patient eligibility to receive home care. During the pandemic this was an invaluable tool to support patients and staff alike.

Additionally, Congress recognized the critical importance of all staff working to the top of their scope of practice when it incorporated the *Medicare Home Health Flexibility Act of 2019* into Division CC, section 115 of Continuing Appropriations Act of 2021, which established the permanent ability of occupational therapists (OT) to conduct the initial and comprehensive assessments for HHAs when OT or other therapy services were part of the plan of care.

There is no foundation for nurses being the only professionals allowed to perform initial and comprehensive assessments when other therapy services are part of the plan of care. This creates an unnecessary burden to providers and can delay the start of care for patients due to continuing shortages in nursing staff. Home health is an interdisciplinary benefit and should rely on the full team to quickly initiate services and fully evaluate patients. All three categories of rehabilitation professionals, OT, physical therapy, and speech language pathologists have curricular requirements included in the general clinical skills required to conduct the initial and comprehensive assessments, both in the identification of immediate care and support needs, as well as the assessment of the patient's general health, psychosocial, functional, cognitive, and pharmacological status. Nothing in the nature of these professionals would put at risk the health or safety of patients, indeed the removal of this regulatory barrier could lead to better outcomes for HHA patients overall.

Regulation: Who May Conduct the Face-To-Face Encounter and Certify Patients for Home Health Services

Trinity Health requests this regulation be updated to conform with statutory authority because, in its current form, it is a burden to home health agencies by not allowing them to utilize non-physician practitioners (NPPs) (nurse practitioners, physician assistants, and clinical nurse specialists) to the full scope of their professional abilities based on the right of states to define those standards.

Code: §424.22(a)(v)(C), §424.22(v)(A)(2) and §484.2

Trinity Health recommends the Administration replace the regulations to align with the flexibilities granted by the CARES Act and eliminate unnecessary barriers to Medicare home health certification. Specifically, CMS should modify §424.22(v)(A)(2) and §484.2 to allow NPPs to certify beneficiaries for home health services in accordance with state laws. Additionally, CMS should amend §424.22(a)(v)(C) to remove the requirement that the certifying practitioner must conduct the face-to-face (F2F) encounter. Instead, the regulations should permit the certifying practitioner to document that a physician or an allowed NPP has conducted the F2F encounter.

The CARES Act was signed into law on March 27, 2020, providing critical relief in response to the COVID-19 pandemic. Among its provisions, the Act included the Improving Care Planning for Medicare Home Health Services Act, which expanded the authority of NPPs to certify eligibility and issue orders for Medicare home health services. Additionally, the Act introduced flexibility regarding who may conduct the F2F encounter, removing the requirement that only the certifying practitioner may perform this function.

On March 30, 2020, CMS issued an interim final rule with comment (IFC), Medicare and Medicaid Programs; Policy and Regulatory Revisions in Response to the COVID–19 Public Health Emergency. This IFC included regulatory revisions under §424.22, granting NPPs the authority to certify and order home health services. However, CMS has not yet issued conforming regulations to reflect statutory flexibility on who may conduct the F2F encounter.

Despite the statutory provisions, the revised regulations at §424.22(a)(v)(C) limit the F2F encounter to the certifying physician or practitioner for patients admitted from the community. Additionally, regulations at §424.22(v)(A)(2) and §484.2 retain a requirement for NPPs to collaborate with physicians when certifying and ordering home health services, even in states that permit independent practice for advanced practice registered nurses (APRNs). This contradicts the CARES Act, which explicitly allows NPPs to practice in accordance with

state laws without requiring physician collaboration and provides flexibility regarding who may conduct the F2F encounter.

The CARES Act clearly reflects congressional intent to authorize NPPs to certify and order home health services for Medicare beneficiaries in accordance with state laws. Furthermore, Congress explicitly granted flexibility regarding who may conduct the F2F encounter, ensuring greater access to care.

CONCLUSION

We appreciate CMS' ongoing efforts to improve payment systems across the delivery system. We welcome the opportunity to inform any future Medicare and are happy to partner with CMS. 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