



August 28, 2026

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-1850-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; Including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program; Request for Information on Strengthening the Standardization and Comparability of Hospital Price Transparency (HPT) Data; Prior Authorization; Accrediting Organization (AO) Deeming for Emergency Medical Treatment and Labor Act (EMTALA); and Notices of Closure of Teaching Hospitals and Opportunities To Apply for Available Slots

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

Dear Administrator Oz,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1850-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.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 133,000 colleagues and nearly 40,000 physicians and clinicians caring for diverse communities across 23 states. Nationally recognized for care excellence and patient experience, the Trinity Health system includes 91 hospitals, 101 continuing care locations, and the second largest Program of All-Inclusive Care for the Elderly (PACE) in the country. Trinity Health has 15 medical groups with 8,900 medical group physicians and providers. With headquarters based in Livonia, Michigan, its annual operating revenue is \$25.4 billion with \$2.9 billion returned to its communities in the form of charity care and other community benefit and community impact programs.

Trinity Health has 12 Clinically Integrated Networks (CINs) that are accountable for 1.8 million lives across the country through alternative payment models. Our health care system participates in 10 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes 8 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). 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.

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.

We are eager to work with Congress and the Department of Health and Human Services (HHS) on alternative payment models that enable providers to move away from fee-for-service and assume responsibility for total cost of care and outcomes for populations served by public programs. Our participation in Medicare demonstration projects, our MediGold MA plans and our PACE programs demonstrate our ability to effectively manage cost and outcomes.

In our detailed comments below, Trinity Health offers the following recommendations:

- CMS should provide fair payment by increasing OPPS payment rates to reflect the increased cost of caring for patients. Specifically, CMS should:
 - Use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10-15% to the market basket to account for what hospitals should have received in 2022 when accounting for inflation.
 - Establish a threshold whereby if the payment differential between what was provided and actual costs is greater than 1.5 percentage points, CMS would retroactively adjust payments for that year.
 - Rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.
- CMS should not accelerate the 340B recoupment, as it is too drastic and would provide hospitals with a -1% OPPS payment through CY2029, wiping out any inflationary payment update for hospitals.
- CMS should not finalize the 340B payment reduction to ASP minus 33.4%
- Extending site neutrality policies to imaging without contrast represents a cut in Medicare payment; we urge CMS not to finalize this policy.
- NPI/Attestation:
 - Define the term "department";
 - Clarify NPI assignment methodology based on physical address;
 - Establish objective documentation standards or utilize existing surveys and certifications processes to minimize the attestation submission and review process burden;
 - Recognize prior-approved attestations;
 - Finalize protections for providers awaiting CMS review; and
 - Adopt a reasonable implementation and enforcement transition, providing flexibility and clear guidance needed to prepare for the January 1, 2028, statutory requirement that each off-campus hospital outpatient department obtain and bill under its own national provider identifier (NPI) and attest to compliance with provider-based requirements, and to take into consideration implications on other areas such as 340B.
- Avoid new administrative burden when finalizing the Software as a Medicals Services payment policy and exempt it from budget neutrality requirements.

- CMS should develop national guidelines outlining patients who are appropriate candidates for inpatient vs outpatient authorization, as well as for patients who are reasonable candidates for same day discharge prior to finalizing policies to remove the IPO list.
- Do not finalize the ASCQR proposal to stratify the All-Cause Hospital Transfer/Admission measure.
- Continue exploring policies that strengthen domestic production of essential medicines.
- Move toward price transparency policies that provide patients with meaningful, actionable information by standardizing reporting requirements and focusing on usability for patients.

Proposed Payment Update

CMS proposes to update OPPS rates by a net 2.4% for CY 2027. This includes a proposed market-basket update of 3.2% and a statutorily required productivity cut of 0.8 percentage points.

Given the extraordinary inflationary environment and continued labor and supply cost pressures hospitals face, Trinity Health is deeply concerned with the proposed payment increase of 2.4% in the FY26 OPPS rule. To maintain access to quality care for Medicare beneficiaries, reimbursement must cover the cost of delivering care. At Trinity Health, 78% of revenue comes from Medicare and Medicaid and 1% is from the uninsured. Unfortunately, Medicare payment rates have not kept up with the increased costs of delivering care across all settings.

The proposed update is woefully inadequate, especially if the 340B accelerated recoupment proposal is finalized because the majority of hospitals would receive a -1% net increase after adjustments—effectively wiping out any inflationary payment update to hospitals through CY2029. This is particularly problematic given the rising labor costs, inflation and other external financial influences, such as uncertainty related to tariff policies and payment cuts from the One Big Beautiful Bill Act (OBBBA) hospitals are facing. Across our footprint, we estimate that approximately 105,000 patients who we serve will lose their Medicaid coverage. Furthermore, once all OBBBA provisions are implemented, we will see an annual \$1 Billion cut to our health system—a cut that is unsustainable and will require us to make difficult decisions.

We urge CMS to provide fair payment and increase payment rates to reflect the increased cost of caring for patients. Specifically, CMS should:

- **Use its special exceptions and adjustment authority to make a one-time retrospective adjustment of 10-15% to the market basket to account for what hospitals should have received in 2022 when accounting for inflation.**
- **Establish a threshold whereby if the payment differential between what was provided and actual costs is greater than 1.5 percentage points, CMS would retroactively adjust payments for that year.**
- **Rebase the market baskets more frequently and at least every three years to ensure the market basket reflects the appropriate mix of services provided to Medicare beneficiaries.**

Proposal to Expedite Recoupment Timeline Under 340B Remedy Rule

Beginning in CY 2018 through CY 2022, CMS instituted a policy to reduce payments for certain providers for separately-payable Part B drugs purchased under the 340B Drug Pricing Program from Average Sales Price (ASP) plus 6% to ASP minus 22.5%. Due to budget-neutrality requirements, this nearly 30% payment cut was offset by increasing payments for non-drug services to all hospitals paid under the OPPS by 3.19%. The U.S. Supreme Court unanimously ruled that the agency's policy was unlawful. The agency subsequently finalized a

remedy that would repay 340B hospitals in one-time lump sum payments totaling \$10.6 billion and reduce the OPPS conversion factor by 0.5% annually beginning in CY 2026 until the full \$7.8 billion was recouped, which was estimated to occur in CY 2041. CMS is now proposing to expedite the timeline for this recoupment by adjusting the reduction in the OPPS conversion factor from 0.5% to 3%.

Trinity Health strongly opposes CMS's proposal to accelerate the recoupment of funds under 42 C.F.R. § 419.32(b)(1)(iv)(B)(12). When CMS finalized the remedy rule, it adopted a 16-year recoupment timeline because it sought to "comply with the statutory budget neutrality requirements while at the same time accounting for any reliance interests and ensuring that the offset is not overly burdensome to impacted entities." CMS also stated that its objective was to restore 340B hospitals to the financial position they would have occupied had the agency not implemented the unlawful payment policy in the first place. Yet, in the proposed rule, CMS now argues that reducing the recoupment period from 16 years to 6 years "better balances" its budget neutrality obligations against hospital burden and reliance interests.

Trinity Health strongly disagrees. If CMS finalizes this proposal, hospitals would face a six-fold increase in the annual recoupment adjustment, from 0.5 percent to 3.0 percent, with little advance notice before CY 2027. Hospitals have developed budgets, financial forecasts, and operational plans based on the existing 0.5 percent adjustment. Imposing such a substantial increase only months before implementation would upend settled expectations, create significant financial uncertainty, and generate serious cash flow challenges for providers already operating under considerable fiscal strain.

CMS's analysis also fails to account for the significant deterioration in hospital financial conditions since the remedy rule was finalized in 2023. Trinity Health, like hospitals nationwide, continues to face escalating labor, supply, pharmaceutical, and operational costs while Medicare and Medicaid reimbursement remain below the cost of providing care. At the same time, changing utilization patterns and demographic trends have resulted in an older, sicker patient population with increasingly complex and costly health care needs. The proposed rule similarly fails to consider the financial impact of the One Big Beautiful Bill Act (OBBBA), which will place additional pressure on hospitals and health systems across the country. **If CMS is truly attempting to balance its budget neutrality obligations against hospital burden and reliance interests, it must account for these significant and well-documented financial realities.** The proposal does not adequately consider the cumulative burden of accelerating recoupment while hospitals simultaneously absorb other substantial Medicare payment reductions and rising costs.

The combined effect of the proposed 2.4% market basket update and the accelerated recoupment of remedy payments would leave many hospitals with an effective payment update of approximately -1% through CY 2029. In practical terms, this proposal would erase inflationary payment updates for hospitals for several consecutive years, an outcome that is simply unsustainable. Trinity Health urges CMS not to finalize this proposal because of the significant harm it would inflict on hospitals' ability to maintain essential services and meet the needs of their communities. **If CMS nevertheless decides to accelerate recoupment, the agency should adopt a more gradual approach, such as increasing the adjustment to 1% in CY 2027, 1.5% in CY 2028, and 2% in CY 2029 and subsequent years. A phased approach would better balance CMS's stated budget neutrality objectives with the financial realities facing hospitals and health systems.**

Ultimately, hospitals should not be made to bear the consequences of CMS' reimbursement cut that the Supreme Court unanimously held unlawful in *American Hospital Association v. Becerra*. Hospitals now

subject to the recoupment could not have declined any additional payments even if they had wanted to. Hospitals should not be punished for CMS' mistakes by having to return funds that they have long since spent, at a time when their finances are already being squeezed by rising costs, inadequate Medicare and Medicaid reimbursement, and other federal policy decisions.

The administrative burden to accommodate the new modifier XX is significant. The total resources and effort needed cannot be determined until the XX modifier is specifically defined by CMS as to which specific drugs would be subject to the modifier.

Payment Reductions for Drugs Purchased under the 340B Drug Pricing Program

CMS proposes that, beginning CY2027, Medicare will pay the average sales price (ASP) minus 33.4% for all separately payable drugs, biologicals, biosimilars and radiopharmaceuticals acquired by hospitals in the 340B program.

Trinity Health is deeply concerned by CMS's proposed reduction to Medicare Part B payment rates for 340B-acquired drugs under the OPPS, which would effectively result in an approximately 40% payment cut for 340B drugs. This policy will lead to a \$109m annual cut to our 340B hospitals. Such a significant reduction would undermine the intent of the 340B Program and disproportionately harm the nation's most vulnerable patients, including those living in rural communities and those who rely on Medicaid for coverage. **The proposal represents another serious financial challenge for safety-net providers and would have far-reaching consequences for the patients and communities we serve. CMS should not finalize this policy.**

Congress established the 340B Program in 1992 to enable participating entities to "stretch scarce Federal resources as far as possible, reaching more eligible patients and providing more comprehensive services. Trinity Health remains deeply committed to advancing this mission through robust implementation of the 340B Program across its covered entities and by reinvesting 340B savings into programs and services that improve access to care. **As part of this commitment, Trinity Health provides approximately \$2.9 billion annually—nearly 10% of our revenue—in community benefit through charity care and other programs that support vulnerable populations, much of which is made possible by 340B savings. Without 340B, this community impact investment is not possible. In addition, the 340B Program allows Trinity Health to expand access to essential services for uninsured, underinsured, low-income, and medically underserved patients throughout the communities we serve.**

The proposed payment reduction would significantly undermine our ability to sustain these investments and would create substantial financial pressures across our health system. Combined with other anticipated Medicare payment reductions, including those stemming from the One Big Beautiful Bill Act (OBBBA), this proposal would further strain providers that disproportionately serve Medicare, Medicaid, rural, and other vulnerable patient populations. **As a result, Trinity Health would be forced to reevaluate and potentially reduce programs and services currently supported through 340B savings, directly affecting patient access to care and community health resources.**

At Trinity Health, approximately 75% of our patients are covered by Medicare or Medicaid, and an additional 2% are uninsured. Savings generated through the 340B Program are essential to advancing our mission of improving the health of our communities. Without these resources, our covered entities would likely be forced to scale back or eliminate services that patients depend upon, requiring many individuals to travel farther for care or forego treatment altogether. Across Trinity Health, 340B savings support a broad range of critical programs and

services, including prescription assistance programs, safety-net health centers, chemotherapy services, and other infusion therapies, all of which could be jeopardized by the proposed payment reductions.

Our hospitals also use discounts available on certain 340B-priced drugs to provide access to medications that would otherwise be financially infeasible to provide. The proposed cuts to Medicare Part B payments for 340B drugs will seriously challenge our ability to continue to offer these and many other programs, challenging our ability to support access to critically needed drugs. In most cases, the magnitude of the loss per patient treatment is significant; in some cases near \$1,000/case. Reducing these already insufficient reimbursement rates by such a significant amount may make provision of these drugs financially infeasible. Trinity Health is concerned that a reduction in the current payment rate for these more expensive drugs could compromise our ability to offer certain therapies, which could compromise beneficiary access and health. Trinity Health is committed to providing the care needed by our patients, but is concerned about the long-term ability to continue providing expensive medications at a financial loss.

Additionally, the proposal could have the unintended consequence of increasing Medicare Part B drug spending overall. Drugs purchased under the 340B Program are excluded from the Average Sales Price (ASP) calculation, while non-340B hospitals generally purchase branded Part B drugs at full market price because manufacturers typically do not offer comparable discounts to hospitals outside the 340B Program. As hospitals potentially lose access to 340B savings, a greater share of drug purchases would occur at higher market prices and become reflected in the ASP calculation. Over time, this dynamic could increase ASP, which serves as the foundation of Medicare Part B drug reimbursement, ultimately driving higher program costs.

CMS has proposed an 8.44% increase to payments for non-drug OPPS items and services to maintain budget neutrality. **If CMS finalizes the proposed payment reductions for 340B drugs, we urge the agency to ensure that any funds redistributed through the budget neutrality adjustment are directed to hospitals whose operations and missions are consistent with the intent of the 340B Program, particularly nonprofit hospitals with a demonstrated commitment to providing charity care and serving underserved populations.** Congress intended the 340B Program to enable participating entities and their patients to benefit from the savings generated through discounted drug pricing. Accordingly, redistributing funds to hospitals that do not participate in the 340B Program would be inconsistent with that Congressional intent. At a minimum, any redistribution methodology should be structured to advance the core purpose of the 340B Program by helping eligible providers stretch scarce resources and furnish more comprehensive services to vulnerable patient populations.

Finally, if CMS moves forward with this policy despite stakeholder concerns, we strongly urge the agency to phase in any payment reductions over multiple years. A gradual implementation approach would provide affected hospitals with time to adapt to the financial impact of the policy and help avoid abrupt reductions in programs and services that are vital to the health and well-being of the patients and communities we serve.

Site Neutrality policy for Imaging Without Contrast

CMS proposes to extend site neutral payment to imaging without contrast APCs (5521-5524). CMS would also apply site-neutral payment to APCs 8004 (Ultrasound Composite), 8005 (CT and CTA without Contrast Composite), and 8007 (MRI and MRA without Contrast Composite).

Trinity Health urges CMS to not finalize this proposal. Medicare already pays less than the cost to deliver care and implementing this site neutral policy is a cut to the Medicare program that will jeopardize hospitals' ability to support hospital-level care in our communities.

Hospital outpatient departments (HOPDs) are providing a hospital-level of services while meeting people where they want and need to have care in their communities. The cost of delivering care in hospitals, including HOPDs, is fundamentally different than other sites of care. HOPD operations include higher capital and facility costs, higher digital health costs, additional quality monitoring, medical staff oversight, protocols, and investment in research that is consistent with a hospital-level of care. HOPDs have costs associated with standby services incurred in 24-hour emergency department settings, which include around-the-clock availability of emergency services, cross-subsidization of uncompensated care, EMTALA and Medicaid, emergency back-up for other setting of care, and disaster preparedness. Physicians frequently refer complex Medicare beneficiaries to HOPDs for critical services, particularly when it comes to the most vulnerable, sickest, and medically complex patients.

Further, HOPDs have more comprehensive licensing, accreditation and regulatory requirements compared to independent physician offices and ambulatory surgical centers (ASCs), all of which increases the cost of care.

NPI/Attestation

CMS proposes to implement requirements from the Consolidated Appropriations Act of 2026 which specifies that no outpatient PPS payment may be made for items and services furnished on or after Jan 1, 2028 by an off-campus PBD unless certain requirements, including having separate NPIs, are met.

We support CMS's objective of promoting compliance with the provider-based requirements found at 42 C.F.R. § 413.65, improving program integrity, and many of CMS' proposals that would reduce the burden of the attestation process. That said, we have significant concerns about the separate NPI requirement and the increased burden it will cause for hospitals and health systems, physicians and other insurers. In addition, and most significantly, the proposed rule does not define what constitutes a provider-based "department" for purposes of obtaining a separate NPI and submitting an attestation. This omission creates substantial operational uncertainty and potential compliance risk.

We urge CMS to implement the recommendations outlined below.

1. CMS Should Define the Term "Department"

The most significant issue presented by the proposed rule is the absence of a clear definition of the organizational unit that constitutes an off-campus outpatient department subject to the new NPI and attestation requirements.

While the proposed rule defines which locations are considered "off-campus," it does not explain what constitutes a "department" within those locations. As a result, hospitals are left without a workable framework for determining how many NPIs must be obtained, how attestations should be structured, and how provider-based operations should be reported in PECOS.

For example, many health systems operate integrated outpatient centers in which multiple service lines share common space, registration, administration, management, staffing resources, medical records systems, and operational oversight. A single location may provide:

- imaging services;
- laboratory services;
- infusion services;
- cardiology services;
- oncology services;
- wound care;
- rehabilitation services; and
- specialty physician clinic services.

The proposed rule does not indicate whether such a location constitutes:

- one provider-based department based on physical address;
- multiple departments organized by specialty;
- multiple departments organized by cost center;
- multiple departments organized by suite;
- or some other organizational construct.

Reasonable providers could reach vastly different conclusions while acting in complete good faith.

CMS should update its proposed definition of “Department of a provider” to include the following:

"All provider-based outpatient operations located at a single physical address, operating under common ownership and governance of the identified main provider." We believe this definition corresponds to how most providers have recorded these locations on their enrollment forms (i.e., Section 4 of the 855A). It would therefore help minimize providers' additional administrative burden. Main providers should also be allowed to determine whether a suite number is part of the physical address.

Such a location-based approach would be objective, operationally feasible, consistent with enrollment systems, capable of uniform national implementation, and less burdensome for both providers and CMS.

Alternatively, CMS should adopt a regulatory safe harbor allowing hospitals to select a reasonable methodology for identifying departments, provided the methodology is documented, consistently applied, and disclosed to CMS.

Absent clarification, hospitals face the possibility that CMS or its contractors could later disagree with the hospital's interpretation and assert overpayments or payment denials based on a term that remains undefined.

II. CMS Should Leverage Existing Medicare and Accreditation Oversight Activities

While Section 6225 requires provider-based attestations as a condition of payment, CMS should implement the statutory requirements in a manner that minimizes duplicative administrative burden on providers and CMS by leveraging existing Medicare oversight mechanisms.

The provider-based requirements at 42 C.F.R. § 413.65 are longstanding program requirements that overlap substantially with matters already subject to review through Medicare Conditions of Participation certification activities, state survey agency reviews, provider enrollment processes, and accreditation surveys conducted by CMS-approved accrediting organizations such as The Joint Commission, DNV, or HFAP. Many of the operational elements associated with provider-based status, including organizational integration, governance,

administration and supervision, clinical oversight (including medical staff credentialing, quality, medical record integration), public awareness, quality management, and operational control, are routinely assessed through these existing oversight mechanisms. In addition, environmental rounding consistent with these surveys would prevent the need for MAC or other review, travel, etc. to view the same physical space.

Accordingly, CMS should avoid establishing a parallel compliance framework that relies on repetitive attestations, extensive documentation submissions, and duplicative audits where equivalent information is already available through existing regulatory and accreditation processes.

We encourage CMS to:

- **accept existing survey and accreditation findings as evidence supporting all or certain elements of provider-based compliance, or make minor adjustments to existing surveys to monitor for additional requirements, allowing certification alone to serve as the attestation;**
- **leverage Medicare enrollment and certification records whenever possible;**
- **limit additional documentation requests to situations involving identified compliance concerns;**
- **or, if certification alone will not suffice for the attestation, provide reduced documentation requirements for accredited organizations; and**
- **coordinate provider-based reviews with existing CMS and accreditation survey activities.**

Such an approach would fulfill the statutory objectives of Section 6225 while reducing unnecessary administrative burden for both providers and CMS.

III. CMS Should Clarify NPI Assignment Requirements

The separate NPI requirement is a statutory condition of payment and therefore warrants detailed implementation guidance. The requirement for separate NPIs raises several serious concerns and CMS has not fully explained how the requirement for off-campus, location-specific NPIs will interact with PECOS enrollment, reassignment relationships, claim submission systems, and existing hospital operational structures.

To prevent greatly increasing hospital regulatory burden and billing confusion, we encourage CMS to take the following steps:

- **Establish a phased-in and transparent implementation process.**
- **Provide sufficient time for provider enrollment changes, payer and provider system configuration, and end-to-end testing, including but not limited to timing to obtain and add to PECOS and a reasonable "notice/correct" period where claims could be rebilled once correction is made.**
- **Exercise enforcement discretion during this transition period for providers.**
- **Create a standardized mechanism that links each off-campus NPI to the hospital's main campus NPI and ensure this crosswalk is available to Medicare contractors and other payers so that systems can recognize the same hospital organization.**
- **Convene stakeholders to identify and resolve claims processing issues.**
- **Clarify any linkage, overlap, or implications of addresses and NPIs utilized for 340B purposes.**
- **Specify that NPIs assigned to an off-campus outpatient department of a provider be location-based and/or address-based (including suite numbers, if applicable) as opposed to service-line-based.**

IV. Prevent Duplicate Efforts to Reduce the Burden of Attestation Documentation Requirements

CMS proposes a detailed attestation process and risk-based review program but provides limited guidance regarding the specific documentation providers must maintain to demonstrate compliance with provider-based

requirements. Trinity Health appreciates that steps will be taken to utilize already existing information to reduce the amount of information that providers will be required to submit as part of the attestation process. As stated above, Trinity Health again encourages CMS to utilize existing surveys, licensure, and accreditation processes for CMS-trusted partners to review documents and compliance while already on site with the main provider and its provider-based departments to reduce both the need for the hospital to upload additional information and for CMS and/or the MAC to review information already reviewed and validated during a licensure, accreditation, or other certification survey.

In the event CMS will not utilize existing processes to review documentation that may be required for submission in the attestation process, the final rule should include:

- **a definitive documentation checklist;**
- **standardized examples of acceptable evidence;**
- **documentation retention requirements;**
- **guidance regarding historical records;**
- **standards applicable to acquired facilities; and**
- **examples of sufficient financial and clinical integration documentation.**

Without objective standards, providers will face uncertainty regarding whether they have adequately substantiated compliance.

V. Existing Approved Attestations Should Receive Deference

Many hospitals previously submitted voluntary provider-based attestations that were reviewed and approved by CMS or Medicare Administrative Contractors.

Trinity Health supports having the authorized official for the main provider attest with a letter to CMS with evidence of the CMS determination attached affirming its continued compliance with § 413.65, as requiring providers to re-attest at this stage would create significant administrative burden without a corresponding program integrity benefit.

VI. Electronic Attestation Process

Trinity Health appreciates CMS's proposal for submitting attestations electronically. We highly encourage CMS to allow as much of the attestation form elements to remain populated for subsequent Provider-Based Facilities based on what is submitted for the first Provider-Based Facility tied to the same Main Provider. Requiring one form, in its entirety, for each individual provider-based department, would be overly burdensome and require submission of duplicative information.

VII. Hospitals Should Not Be Penalized for CMS Review Delays

We appreciate CMS's proposal recognizing that providers who timely submit attestations in good faith should not lose eligibility merely because CMS review remains pending.

We strongly support this policy and request that it be finalized.

VIII. CMS Should Phase-In Enforcement

The operational changes required by Section 6225 are substantial. Health systems must inventory provider-based locations, obtain NPIs, revise enrollment records, update billing systems, educate staff, and prepare supporting documentation.

CMS should therefore establish a transition period of no less than one year during which technical mistakes, enrollment discrepancies, and minor attestation deficiencies may be corrected without loss of payment eligibility, provided providers demonstrate good-faith efforts toward compliance.

Software as a Medical Service (SaMS)

CMS is proposing an interim payment policy for software-based medical services with algorithmic analyses to recognize that certain software products independently furnish a distinct clinical service worthy of independent payment.

The policy as proposed has the potential to shift AI and algorithm-driven clinical software from an IT expense to a separately reimbursable medical service. It is also likely to improve ROI and offset compute expense if reimbursement for the use of these tools becomes more predictable. **However, Trinity Health is concerned the policy will lead to a greater focus on documentation, coding, and charge capture; thereby creating more administrative complexity and increasing burden. We urge CMS to consider this administrative complexity/increased burden when finalizing the proposed rule and exempting this increase from budget neutrality policy so that providers can continue making investments in AI.**

Inpatient Only List

In CY 2026, CMS finalized a policy to phase out the IPO list over three years. For CY 2027, CMS proposes to continue this policy by removing an additional 637 services from the following clinical families: auditory, digestive, endocrine, female genital, hemic and lymphatic systems, integumentary, male genital, maternity care and delivery, mediastinum and diaphragm, respiratory and urinary. These services represent approximately half of the 1,438 services currently remaining on the list. CMS indicates that the remaining 801 IPO services are generally more complex and will require additional consideration but still expects these remaining procedures to be evaluated for removal in CY 2028.

While we do believe physicians should be able to use their clinical judgement in determining where patients receive care, we have concerns with the inconsistencies and barriers to care this proposal may create. If not implemented correctly, this policy may lead to delayed care and unintended consequences. Trinity Health urges CMS to work with stakeholders to develop a longer-term, data-driven approach to this significant change in Medicare coverage requirements that accounts for patient safety, quality and outcomes. While some private health insurance plans already require that some procedures on the IPO to be provided in an outpatient setting for commercial populations, they have different motivations for their requirements and the Medicare population can vary significantly from the commercial population in terms of comorbidities and risks of complications. Additionally, we urge CMS to exempt hospitals that utilize certain clinical decision support tools from patient status review for the two-midnight policy. The technology exists to achieve the same program integrity and patient safety goals as the two-midnight rule without the uncertainty around coverage for patients.

CMS must acknowledge the administrative burden this proposal will create from MA plans and commercial payers. As evidenced by services removed from the IPO list in recent years, health plans use less expensive settings as the default that require lengthy appeal and prior authorization processes to overcome these defaults; this makes it harder to ensure patients receive care in the safest, most appropriate setting. If a physician determines a patient would be best served in a specific setting, MA plans (and commercial payers) should not create barriers to receiving care in the clinically-appropriate setting. **To mitigate these practices, we urge CMS to develop national guidelines outlining patients who are appropriate candidates for inpatient**

vs outpatient authorization, as well as for patients who are reasonable candidates for same day discharge. We believe this would create standardization and help mitigate denials from payers.

As a technical recommendation for what's been implemented to date, CMS needs to provide HCPCs codes for implantable devices for procedures such as cardiac valve and total hip/total knees so that hospitals can properly report these services under Revenue Code 278.

Accrediting Organizations Enforcement of Certain EMTALA Requirements

CMS proposes to permit accrediting organizations (AOs) such as the Joint Commission to assess hospital compliance with EMTALA's administrative requirements (e.g., signage and record keeping) as part of its routine accreditation and reaccreditation surveys. CMS would continue to enforce all other EMTALA requirements, including those for medical screening examinations, stabilizing treatment and appropriate transfers, using its existing processes.

Trinity Health has significant concerns regarding provisions that could effectively expand the role of AOs beyond assessment of administrative processes and into the identification, investigation, or reporting of potential EMTALA violations.

In particular, proposed § 488.5(vi), which permits AOs to refer violations of 42 CFR § 489.24 to CMS, appears to create a pathway for AOs to function as de facto EMTALA enforcement entities. We believe this authority blurs the distinction between assessing compliance with administrative requirements and evaluating whether an actual EMTALA violation has occurred. EMTALA investigations have historically been conducted by State Agencies and CMS through specialized processes that recognize the complexity and fact-specific nature of emergency care delivery.

EMTALA compliance and potential violation determinations cannot be effectively assessed in isolation from the broader clinical and operational context in which care is delivered. Evaluating whether a hospital appropriately met its EMTALA obligations requires careful consideration of numerous factors, including:

- The services available at the hospital and within the health system at the time care was needed.
- The specific time, day, and circumstances under which the patient presented.
- Dynamic capacity assessments, including available beds, staffing, specialty coverage, equipment, and other resources.
- Clinical decision-making occurring in real time.
- Determinations regarding what care and disposition options were clinically appropriate and in the best interest of the patient under the circumstances.

These assessments are often highly nuanced and require review of the complete clinical picture rather than isolated documentation elements or retrospective observations.

If CMS finalizes the policy, the agency should clarify that AO's authority is limited to assessment of EMTALA administrative requirements and does not extend to identifying, investigating, or referring potential EMTALA violations absent consultation through established CMS enforcement processes. Such clarification would preserve the integrity of EMTALA oversight while ensuring that compliance evaluations are conducted with the appropriate clinical expertise and contextual understanding necessary for fair and accurate review.

In addition, any reviewers assessing EMTALA-related requirements, whether employed by State Agencies or AOs, should possess substantial expertise in emergency care delivery. The complexities of emergency department operations, transfer practices, specialty coverage, patient acuity, and capacity management require reviewers with relevant clinical knowledge and experience. Without such expertise, there is a significant risk that compliance determinations may fail to account for the realities of emergency care and hospital operations, leading to inaccurate conclusions regarding a hospital's actions.

ASC Quality Reporting

CMS requests feedback on whether it should stratify the All-Cause Transfer/Admission measure in the ASC Quality Reporting Program (ASCQR) by phase of care — that is, report measure results by patients in the pre-procedure, intra-procedure or post procedure phase — to improve attribution and interpretability across the diverse range of ASC services.

Trinity Health does not support the proposed stratification of the All-Cause Hospital Transfer/Admission at this time.

Consideration of Separate Payment for Domestic Procurement of Essential Medicines

Trinity Health applauds CMS's efforts to explore policy options that strengthen domestic production of essential medicines and improve the resilience of the U.S. pharmaceutical supply chain. We support CMS's proposal to include FDA-approved medicines from the ARMI Essential Medicines List that have existing U.S. finished dose form ("FDF") production and do not contain active pharmaceutical ingredients ("API") sourced from countries identified as foreign adversaries under 15 CFR 791.4. We also support CMS's decision to prioritize non-substitutable sterile injectables and generic antibiotics that have been in shortage. **As CMS evaluates future expansions of the eligible drug list, we encourage the agency to continue applying criteria consistent with the prioritization framework reflected in Table 80 of the proposed rule.**

We encourage CMS to develop a program-specific definition of "domestic" that aligns with the payment policy's intended tiered structure and allows for the CMS outlined payment adjustment to apply to both FDF drugs manufactured in the U.S. with U.S. API and non-U.S. API. CMS's definition should ensure that products are categorized based on the manufacturing characteristics the agency seeks to incentivize, rather than on a Customs country-of-origin analysis developed for different purposes.

Trinity Health appreciates CMS's consideration of both the claims-based and cost-report-based approaches for calculating and distributing payment adjustments for eligible essential medicines and we encourage the agency to ensure that participation requirements remain as streamlined as possible and that documentation and reporting obligations are appropriately balanced with the intended policy benefits. A straightforward and administratively feasible payment methodology will help promote provider participation and support the program's broader objective of encouraging domestic sourcing of essential medicines.

RFI on Strengthening the Standardization and Comparability of Hospital Price Transparency Data

General comments on price transparency

Trinity Health strongly supports efforts to advance healthcare price transparency and empower patients with meaningful, actionable information about their anticipated medical costs before they receive care. Patients deserve clear, accurate, and understandable cost estimates that include not only the provider's charges, but also individualized information regarding deductibles, copayments, coinsurance, and other cost-sharing obligations.

Access to this information is essential to helping patients make informed healthcare decisions, avoid unexpected medical bills, and better plan for their financial responsibilities.

Achieving the goals of price transparency requires a regulatory framework that is practical, standardized, and equitable for all stakeholders. A significant challenge providers face today is that payment terms also vary based on coverage and payment policies created and controlled by payers. Requiring hospitals to independently interpret and translate these payer-specific policies into standardized public reporting formats places an undue burden on providers and creates substantial risk for inconsistency.

In addition, most payer/provider contracts contain payment logic, not expressed as rates resulting in variation from hospital to hospital regarding how information is classified, reported and displayed. Examples include changes to rates based on the number of services provided during an encounter and “lessor of” provisions. Standardization on how this information is publicized will enable more accurate and reliable information for patients. Even better is to continue to allow providers to use price estimator tools as an alternative to rate files.

We believe CMS's efforts to establish more nationally standardized reporting categories represent an important first step toward greater consistency and transparency. However, additional standardization is needed. Increasingly, providers, vendors, and data aggregators are being forced to interpret what they believe CMS intends rather than relying on clearly defined national reporting standards. CMS should establish more explicit and uniform definitions, methodologies, and reporting requirements that can be applied consistently across the industry.

Moreover, despite our best efforts to provide accurate and meaningful pricing information, inaccurate pricing information published by payers can significantly reduce the usefulness of the information available to patients. Because patients rely on that information when making healthcare decisions, providers should have the right to challenge inaccurate information published by payers.

Successful price transparency depends on patients receiving accurate, consistent, and understandable information regardless of where they seek care. To achieve this objective, CMS should continue to encourage hospitals to implement, develop, and maintain price estimator tools and reduce the complexity of MRFs. This approach will better serve patients while reducing administrative burden and improving accessibility to healthcare pricing information across the healthcare system.

Machine Readable Files (MRFs)

What information is needed for users of the MRF to fully understand contract terms related to outlier payments, stop-loss, rate-tiering, carve-outs, and other adjustments that occur across hospital items and services?

Many hospital-payer contracts rely on complex reimbursement methodologies that cannot be accurately represented through a code-by-code format. While hospitals are able to report discrete fee schedule rates on MRFs, the files are less effective at capturing the business rules and payment logic that drive significant portions of hospital reimbursement. They are also unable to capture payer policies, which can substantially alter reimbursement.

Contract provisions such as revenue code carve-outs, stop-loss arrangements, outlier payments, case rates, and other adjustments often apply across multiple services, encounters, or claim types rather than to individual procedure codes. As a result, these methodologies cannot always be translated into a standardized fee schedule structure without losing context or creating potentially misleading representations of the underlying contract terms.

The structure and complexity of MRFs suggest they are designed primarily for third parties that aggregate, normalize, and analyze pricing information rather than for individual consumers making healthcare decisions. Patients are far more likely to benefit from personalized price estimator tools that provide actionable information regarding their anticipated out-of-pocket costs, including deductibles, copayments, coinsurance, and other cost-sharing obligations. Personalized price estimator tools made available by hospitals today can offer this information, which is meaningful to patients and displayed in a format they can understand and use.

As such, CMS should continue to support hospitals in their development and maintenance of these tools. Moreover, and rather than requiring increasingly prescriptive MRF reporting structures, CMS should allow hospitals to report and explain complex reimbursement methodologies in their MRFs through free-text fields when necessary.

Further standardization of outlier payments, stop-loss provisions, carve-outs, and similar adjustments could unintentionally reduce transparency by oversimplifying contract terms that vary significantly across payers and markets. Maintaining flexibility in reporting these methodologies will better preserve accuracy, reduce administrative burden, and support the ultimate goal of transparency: providing patients with clear and understandable information about the cost of their care. CMS could require payers to submit corresponding contract methodology information through Transparency in Coverage (TiC) files to enable CMS to reconcile both datasets and avoid duplicative reporting where identical information already exists within payer transparency files.

What additional contracting or payment adjustments affect payer-specific negotiated charges at the item or service level, across items and services, or at the contract level, and should that information be encoded in the current data elements provided? If not, what changes to the current formats would be advised to capture this information in a standard manner?

Many additional payment methodologies affect negotiated reimbursement but do not align, on a one-to-one basis, to a specific item or service in the MRF. Examples include case-rate outliers, revenue code carve outs, multiple procedure language, and other contract-specific payment rules that apply and change under an almost innumerable number of patient-specific circumstances. These provisions often span multiple services, claims, or episodes of care and can vary significantly both within and across payer contracts. Moreover, payer-specific negotiated charges are often directly and substantially affected by payer policies, which are unilaterally imposed and applied by payers. Hospitals often have little to no input into how these policies are developed, interpreted, and applied, and are unable to account for them in MRFs.

The MRF is fundamentally a data table designed to report rates; however, these payment terms function as contract-level reimbursement logic. As such, we do not believe these methodologies can be effectively standardized within MRFs because the context needed for their application often depends on non-discrete data that dependent on the circumstances of an individual case. We therefore believe that price estimator tools are more helpful and effective at conveying hospital pricing to patients.

Are there challenges in parsing and categorizing the free text fields when analyzing MRFs? If so, what parameters or requirements would facilitate parsing and categorizing free text fields?

We encourage CMS to review existing free-text submissions and establish a limited set of standardized categories for commonly reported contract provisions, such as outlier payments, stop-loss arrangements, rate tiers, and carve-outs, into standard drop downs. Hospitals could select from these categories where applicable, improving consistency and reducing variability in reporting.

At the same time, as long as MRFs remain, it is essential that CMS preserve flexibility for hospitals to explain complex reimbursement methodologies that do not fit within standardized categories. Many payment arrangements are highly variable and contract-specific, making them difficult to fully capture through structured fields alone. For this reason, free-text fields should remain available, including an "other" category, to allow providers to accurately describe unique payment terms and methodologies.

Thus, a hybrid approach that combines standardized categories for common concepts with the flexibility to provide narrative explanations for complex or unique arrangements would best support transparency, improve data usability, and maintain the accuracy of reported information.

Are there categories of information or topics consistently included in free text fields that may be standardized through the addition of new data elements? If so, what topic areas should be considered?

If CMS chooses to pursue greater standardization of MRFs, including of the free-text fields therein, we encourage the Agency to work collaboratively with providers by convening a stakeholder workgroup that includes the American Hospital Association (AHA), hospitals, health systems, and other industry experts. Engaging those responsible for reporting and maintaining this information will help ensure that any standardized categories are practical, accurately reflect real-world contracting arrangements, and advance transparency without creating unnecessary burden or reducing the accuracy of reported information.

Should CMS require more structured reporting of payer, plan, product, network, and employer (as applicable) information across hospital MRFs, and if so, which elements should be required? Are there existing identifiers for payers and plans, to which hospitals have access, that should be incorporated in the MRF?

Hospitals do not develop, maintain, or control this information and do not have access to standard payer or plan identifiers. More structured reporting could improve consistency and usability of the data, particularly if CMS provides standardized naming conventions for payers, plans, products, networks, and employers that can be readily incorporated into hospital systems and vendor platforms.

However, the primary challenge is the absence of a nationally recognized, standardized identifier for the thousands of payer plans, products, and networks currently in the market. Without such identifiers, hospitals must manually interpret, map, and reconcile this information, which limits comparability across organizations and increases administrative burden. As a result, additional reporting requirements alone are unlikely to achieve CMS's comparability goals.

We encourage CMS to work with payers, providers, health IT vendors, and other stakeholders to develop a national payer-plan-product identifier framework that can be used consistently across the healthcare ecosystem. Payer participation will be essential to ensuring the accuracy and sustainability of such an approach.

What additional information should we consider to enhance the utility and comparability of the MRF data?

CMS should continue focusing on ways to make transparency information more understandable and actionable for patients. One opportunity would be for CMS to develop simple, consumer-friendly educational resources that explain common hospital reimbursement methodologies and pricing concepts, such as fee schedules, DRGs, case rates, deductibles, copayments, and coinsurance.

Hospitals could then link directly to these CMS-developed resources within their transparency tools and websites, creating a consistent national approach to patient education. Improving patient understanding of how healthcare reimbursement works would help patients better interpret the pricing information already being made available.

Consumer Friendly Display

Should CMS revisit the number and types of CMS-specified shoppable services? What are the advantages and disadvantages of increasing or decreasing the number of shoppable services? Are there specific shoppable services that CMS should include, exclude, or update on the list of 70 CMS-specified items and services?

CMS should revisit the distinction between the 70 CMS-specified shoppable services and the hospital-selected shoppable services. The original intent of the CMS-specified services was to focus on common, relatively predictable services that patients could reasonably shop for. However, significant advances in hospital price estimator tools now allow providers to generate more personalized and accurate estimates than were possible when the requirements were first established.

CMS should consider providing hospitals with greater flexibility to identify and maintain a set number (i.e., 300) of shoppable services that is most relevant to the patients and markets they serve. Allowing hospitals to select up to a defined number of shoppable services would enable providers to tailor transparency information to local utilization patterns, patient needs, and clinical practices, which can vary significantly across regions.

The primary advantage of this approach is that it would make consumer-facing transparency tools more meaningful and relevant. Hospitals could focus on the services most commonly sought by patients in their communities rather than on a fixed national list that may not reflect local demand. It would also reduce the administrative burden associated with maintaining separate categories of shoppable services.

More importantly, personalized price estimator tools have become the most effective way to provide consumers with actionable cost information. These tools can account for differences in services ordered and benefit design in ways that static shoppable service lists cannot.

What would be the advantages and/or disadvantages of requiring hospitals to submit a shoppable services file? Alternatively, what would be the advantages and/or disadvantages of removing the deemed compliance for the price estimator tools? Does the current incongruity in how hospitals display shoppable services, with some posting a shoppable services file and others utilizing a price estimator tool, make it more difficult for consumers to actually compare prices for shoppable services across different hospitals? What positive or negative effects would consumers experience if the price estimator tool alone were no longer considered compliant?

CMS should not get rid of deemed compliance for price estimator tools. Hospitals offering these tools have invested substantial resources to create and maintain them, and many allow patients to generate payer-specific estimates for those payers with which the hospital has negotiated rates. Deemed compliance encourages continued maintenance and development of these tools through continued curation not only of the services offered but of their overall design, allowing hospitals to match the same with their patient population. For example, hospitals in urban and rural markets may not only want to select different services to present via their

respective tools but may also wish to customize the design and certain functionalities based on their respective patient populations.

Thus, and as previously stated, these tools provide patients with the most meaningful and personalized cost information, and deemed compliance allows hospitals to be nimble, innovative, and continually improve the tools to better meet patient needs. Moreover, deemed compliance continues to offer consideration for those hospitals that choose to go above and beyond the baseline consumer friendly display requirements.

If CMS is concerned about variation in how transparency information is displayed, a better approach would be to include certain additional requirements at 45 CFR 180.60(b) that are meaningful to patients. For example, Trinity Health supports a requirement that a hospital's price estimator tool include notification of and link to a hospital's financial assistance policy.

Which data elements are important for consumers to make comparisons between hospitals? Would a standard shoppable services file template make the information more comparable? How could a shoppable services file indicate the ancillary services that are included in or excluded from the price?

Static files are not the most effective way for consumers to compare costs. Most patients are unlikely to download and analyze large data files or compare hospitals on a line-by-line basis. Instead, consumers benefit from interactive price estimator tools that guide them to the information they need and present cost estimates in a clear, actionable format.

CMS should continue to allow flexibility for hospitals to develop transparency tools that meet the needs of their patient populations. Patients don't want files—they want interactive tools that can provide the information they need to make an informed decision about their health care. Providing relevant, personalized information through interactive tools is more likely to help consumers make informed decisions than expanding or further standardizing static shoppable service files.

How should hospitals present ancillary items, implants, and bundled services so consumers better understand total expected costs? What approaches most effectively distinguish included versus excluded services?

Hospitals bundle and package services in price estimator tools in a manner that has historically corresponded to the services that patients need for a particular procedure/service.

Other recommendations

A critical prerequisite to improving transparency and comparability is the establishment of a standardized national payer-plan identifier. Without a unique identifier used consistently across all payers and providers, hospitals must manually interpret and map thousands of payer plans, products, and networks, resulting in variation and limiting meaningful comparisons across organizations. A standardized payer identifier for each payer would create a common foundation for transparency reporting and is essential to achieving consistent, comparable data across the healthcare system.

Comparability can be achieved through centralized standards. CMS should consider freezing core reporting elements for a minimum 3-year period and avoid annual structural redesigns of the MRF requirements as the agency thinks through a redesign of price transparency requirements and how to ensure they provide patients with meaningful information. We also recommend CMS develop/strengthen certified validation software that hospitals can use prior to MRF submission and establish safe harbor protections for good-faith technical errors.

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