Trinity Health

September 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-1834-P; Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs; Overall Hospital Quality Star Ratings; and Hospital Price Transparency

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

Dear Administrator Oz,

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-1834-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, 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.
- Trinity Health does not support finalizing requiring hospitals to report the median payer specific charge negotiation by DRG with MAOs, as this could result in new pricing distortions.
- CMS should not accelerate the 340B clawback, as it is too drastic and would provide hospitals with just a +0.06% OPPS payment increase when coupled with the proposed insufficient market basket update.
- CMS should not finalize the 340B hospital drug acquisition survey.
- Extending site neutrality policies to drug administration represents a cut in Medicare payment; we urge CMS not to finalize this policy.
- 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 prior to finalizing policies to remove the IPO list.
- For Skin substitutes, we encourage CMS to analyze cost data, wholesale acquisition cost (WAC) and average sales price (ASP) and update OPPS reimbursement rates for ambulatory payment classifications 6001, 6002, and 6003 quarterly throughout CY2026 to reflect differences in costs in a timely fashion and to mitigate clinical practice shifts due to inadequate reimbursement.
- We support finalizing the policy that would permanently revise the definition of direct supervision to allow virtual supervision services.
- The proposed price transparency policies should not be finalized. We recommend instead that:
    - CMS focus on a price estimator tool, as this would be much more meaningful for patients and will do a better job providing estimates on out-of-pocket coverage.
    - Should CMS finalize the proposed policy, we recommend the agency require the inclusion of the mean rather than the median data element as proposed.
    - CMS should maintain the existing attestation language.
    - If CMS finalizes these policies as proposed, we urge the agency to extend the compliance date to 1/1/28 to ensure that hospitals and their vendors are able to make changes to their systems and come into compliance.
- We are supportive of the proposed cross program quality measure that would remove the COVID-19 HCP vaccination measure.

- We do not object to the removal of the Hospital Commitment to Health Equity measure as measures such as this do not contribute to improved patient outcomes. However, CMS should still encourage voluntary documentation of existing Z-codes for research purposes, including many of the research initiatives outlined in the Make America Healthy Again (MAHA) agenda.
- We have concerns with the proposed OQR measure on Emergency Care Access & Timeliness electronics clinical quality and instead recommend CMS consider redesigning the measure and push the mandatory reporting back by two years.
- The Extraordinary Circumstances Exception policy should not be shortened from 90 to 30 days, as past experiences with catastrophic events have shown that even a 90-day timeframe can be insufficient. We recommend aligning with the 60-day policy finalized in the CY26 IPPS rule.
- We strongly recommend that CMS put in place additional testing of the proposed Hospital Star Ratings policy prior to finalization to ensure the opportunity for course correction prior to full implementation and public reporting.

Proposed Payment Update

CMS proposes to update OPPS rates by a net 2.4% for CY 2026. 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 clawback proposal is finalized because the majority of hospitals would receive a mere +0.06% net increase after adjustments. 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.

While CMS' estimate of labor expense increases this year does align with private sector data for the first time in four years, we encourage CMS to continue expanding its data set to ensure the use of accurate, timely data that reflects real labor costs such as contract workers being used to fill staffing shortages, or rises in wages associated with attracting and retaining hospital employees.

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.**

Market Based IPPS Weights

The rule would require hospitals to report the median payer-specific charge negotiated by MS-DRG with Medicare Advantage Organizations on its Medicare cost report. The agency's goal is to reduce the reliance on the hospital chargemaster and inject more market pricing into Medicare payment rates. CMS plans to use the submitted information to set IPPS relative weights beginning in FY 2029. Further, CMS believes there would be minimal initial impacts from this change because of correlation between the MAO rates and Medicare FFS rates.

While Trinity Health supports improving the efficiency of care and ensuring payments are set appropriately, using negotiated rates for the MS-DRG relative weights has several significant flaws and, **therefore, we do not support CMS finalizing this proposal for the following reasons:**

- **The policy could result in new pricing distortions rather than driving market-based IPPS rates. While CMS highlights its concerns that hospital chargemasters do not reflect true market costs, CMS presumes that MS and commercial rates reflect competitive negotiations between hospitals and private health insurance plans. While this may be the case for some markets and individual hospitals, other factors may contribute to the rates paid by MA plans and private insurers, including whether rates are set based on a percentage of Medicare fee-for-service or the level of competition (between either hospitals or payers) in the individual hospital's market.**
- **This proposal does not adequately factor in the ways in which value-based contracts between payers and providers would be incorporated into market-based Medicare relative weights.**
- **Many MA contracts are a percentage of the Medicare FFS rate; this seems like a circular exercise that won't provide CMS with helpful information to inform rate setting. In addition, yield from MA contracts is often well below the negotiated MA rate and would further distort data.**

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 2%.

Trinity Health strongly opposes CMS's proposal to accelerate the clawback of funds under 42 § 419.32(b)(1)(iv)(B)(12). When it codified a 16-year timeline in the Final Remedy Rule, CMS stated that 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." In suddenly changing course, CMS now asserts that it "insufficiently accounted for" what it calls the "main premise of the Final Remedy rule": the need to return 340B hospitals to the financial position they would have been if CMS never implemented its unlawful policy in the first place. According to the proposed rule, a 6-year time frame "better balances that goal and [its] budget neutrality obligations against hospital burden and reliance interests."

This analysis gets the balancing completely wrong because it does not adequately account for changes on the burden/reliance interest side of the equation. *First*, the proposed rule states: "Because we are proposing this policy in advance of CY 2026 and before any rate reductions go into effect for OPPS and Medicare Fee for Service payments, any reliance interests hospitals have in a policy that has not been implemented yet for these payment systems would be minimal." This reasoning reflects a fundamental misunderstanding of how hospitals operate in the real world.

Like all hospitals and health systems, Trinity Health makes planning decisions about budgets based on what we expect to occur in future years. We therefore began planning for this clawback as soon as CMS announced it in 2023. And as part of those medium- and long-term planning decisions, we factored in a 0.5 percent clawback.

It therefore makes no difference that those rate reductions have not yet gone into effect. If the agency finalizes this unexpected increase from 0.5 percent to 2.0 percent just two months before 2026, the budgets we have produced based on that 0.5 percent figure will be negatively impacted, upsetting settled expectations with little time to readjust and creating serious cash flow problems. That is the paradigmatic reliance interest CMS is wrong to state that those interests are "minimal."

We further note that there are downstream impacts of these cuts that further compound the financial challenges. With both the initial ASP change and clawback, MA payers have taken advantage and have largely declined to repay like CMS, creating a windfall for MA payers on the backs of hospitals.

Relatedly, the agency's balancing fails account for adverse financial trends since 2023. As a general matter, Trinity Health's costs have increased and are continuing to trend in the wrong direction. Like all hospitals, our government reimbursements continue to remain below the cost of treating patients. And also like other hospitals, shifts in care patterns will present us with older, sicker populations with more complex, chronic conditions that are more costly to care for. In addition, the proposed rule does not consider the recent passage of the OBBBA, which will have direct, adverse impacts on our health system's finances that we outlined above. **Accordingly, if the agency is truly trying to balance its purported "budget neutrality obligations against hospital burden and reliance interests," it cannot ignore the effects of the OBBBA or these other financial trends.**

The proposed rule fails to account for the burdens that it will impose on hospitals--the final rule *must* discuss and account for changes on the reliance interest and burden that would result if this proposal were finalized.

Finally, the proposed rule fails to consider a sufficient number of less harmful alternatives. It states that the agency considered an even faster clawback period (3 years). But the agency nowhere explains why it arbitrarily chose that alternative when others exist. The agency easily could have considered timelines between 6 and 16 years. It could have—and should have—considered periods *longer* than the existing 16-year timeframe to better account for post-OBBBA realities. The agency should consider reasonable alternatives and explain why, in its view, 6 years achieves the needed balancing better than these other timeframes.

Ultimately, Trinity Health urges CMS to not finalize this proposal as it is too drastic and would negatively impact the ability of hospitals to serve their communities. Coupled with the inadequate market basket update of 2.4%, the majority of hospitals would receive just a +0.06% net increase.

Hospital Drug Acquisition Cost Survey

CMS is proposing to conduct a hospital drug acquisition cost survey that will open starting at the end of CY 2025, and responses will be collected into early CY 2026. Results of the survey will be compiled and used to set payment rates for covered outpatient drugs in the CY 2027 rulemaking.

340B hospitals deliver 77% of all hospital care for Medicaid patients and 67% of all hospital uncompensated and unreimbursed care. 340B hospitals devoted 29% more of their resources to low-income and uninsured patients in 2022 than non-340B hospitals, an increase from a 17.5% gap in 2019. Significant Medicaid changes under OBBBA will result in 340B hospitals subsidizing even more health care services for newly uninsured low-income individuals. Moreover, while 340B hospitals support the Inflation Reduction Act's efforts to reduce drug costs for patients, 340B hospitals will lose even more 340B savings due to reimbursement cuts on selected drugs. 340B hospitals already run tight, often negative, operating margins, and these collective changes will reduce our financial resources. Additional cuts to Medicare Part B drug reimbursement would significantly undermine 340B at a time it is most critical to supporting the safety net.

CMS should abandon its proposal to conduct a drug acquisition cost survey of all hospitals paid under the OPPS. Requiring a survey at the level of detail that CMS proposes would place a significant burden on hospitals at a time when they are already facing significant payment cuts from the OBBBA and have high levels of regulatory burden. The survey will inflict unnecessary costs on hospitals and their employees, all with the goal of cutting Medicare payments to certain groups of hospitals beginning in CY 2027. **Furthermore, limiting data collection to hospitals alone would depict an incomplete picture of acquisition costs. To ensure accuracy and comprehensiveness, CMS would also have to engage drug manufacturers and distributors and other entities involved in the supply chain to incorporate data points such as the cost of goods sold and any applicable discounts and rebates.**

Cost acquisition surveys are costly. The proposed rule estimates that each hospital will require 73.5 hours to complete the survey at an approximate cost of $4,000. In its 2006 report to Congress about the lessons learned when conducting hospital acquisition cost surveys, the Government Accountability Office stated that the surveys "created a considerable burden for hospitals." Based on our experience with surveys of this kind, this is absolutely true. **The proposed rule's estimate grossly underestimates both the cost and time required to complete any survey.**

CMS appears to be conducting this survey in service of reducing Medicare reimbursements in CY 2027 and beyond. But Medicare payments *already* lag far behind the costs hospitals incur for providing care to Medicare beneficiaries. Medicare covers just 83 cents for every dollar spent by hospitals in 2023, resulting in over $100 billion in underpayments. From 2022 to 2024, general inflation rose by 14.1%, while Medicare net inpatient payment rates increased by only 5.1%—amounting to an effective payment *cut* over the past three years. And in December 2024, the Medicare Payment Advisory Commission noted in a preliminary presentation to Commissioners that hospital Medicare margins had sunk to an all-time low of negative 12.6% and were projected to remain at that level in 2025. An additional Medicare cut resulting from this proposed survey would be unsustainable

Survey results are of limited value and are focused on only a single piece of the larger supply chain and complicated cost structure. The specific questions that CMS asks only highlight those limitations. *First*, CMS asks whether it "should make responding to the survey a mandatory requirement of all hospitals paid under OPPS," but CMS identifies no statutory authority for such a mandatory requirement. Section 1833(t)(14)(D)(iii), the only statute cited in that discussion does not provide the agency with the authority to *mandate* hospital responses. All it does is set forth the requirements for a survey. If Congress wanted to require hospital participation in a drug acquisition cost

survey or allow the Department of Health and Human Services Secretary to take enforcement action for a non-response, it would have done so, as it has in other contexts. **Absent such statutory authority, and absent any way to enforce a manufactured response-requirement, any cost acquisition survey should be voluntary**.

In addition, CMS "welcome[s] comment on how we might propose to interpret non-responses to the survey." The proposed rule includes four options that the agency could use to interpret a hospital's non-response to its survey, but *none of these options* would satisfy the statutory requirement that a survey "…have a large sample of hospitals that is sufficient to generate a statistically significant estimate of the average hospital acquisition cost for each specified covered outpatient drug." **Proposed interpretations of non-responses would yield inaccurate data that is in no way "statistically significant."**

Site Neutrality policy for Drug Administration in Off-Campus HOPDs

CMS proposes to extend site neutral payment method for drug administration services delivered in previously excepted off-campus provider-based departments (APCs 5691-5694) and is seeking comments on additional services furnished on-campus clinic visits that could be also subject to site neutral payment methodology. CMS is also seeking feedback on the development of a more systematic process for identifying ambulatory services at high risk of shifting to the hospital setting based on financial incentives rather than medical necessity.

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.

Inpatient Only List

CMS proposes to phase out the IPO list over three years. This would begin in CY 2026 with the removal of 285 mostly musculoskeletal type services, but also includes 16 non-musculoskeletal services (cardiovascular, lymphatic, digestive, gynecological and endovascular), and completing the elimination of the IPO list by Jan. 1, 2029. Given this proposal, the agency further proposes to eliminate the criteria used to determine whether procedures should be removed from the IPO list.

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.**

Two-midnight Rule Medical Review Activities Exemptions

For CY 2026, CMS proposes to continue the existing policy that exempts procedures removed from the IPO list under the OPPS from certain medical review activities related to the two-midnight policy. Per this policy, procedures removed from the IPO list are exempted from site-of service claim denials, Beneficiary and Family-Centered Care Quality Improvement Organization referrals to Recovery Audit Contractor (RAC) for persistent noncompliance with the two-midnight rule, and RAC reviews for “patient status” (i.e. site-of-service) until claims data demonstrates that the procedures are more commonly billed in the outpatient setting than the inpatient setting.

Trinity Health supports this policy.

Modification of Payment Structure for Skin Substitute Products

CMS proposes to pay separately for certain groups of skin substitute products as supplies when they are used during a covered application procedure paid under the Physician Fee Schedule in the non-facility setting or under the OPPS. This proposal includes grouping skin substitutes that are not drugs or biologicals using three Food and Drug Administration (FDA) regulatory categories (PMAs, 510(k)s, and 361 HCT/Ps) to set payment rates. To accomplish this categorization and incorporation into OPPS payment policy, CMS proposes to create three new APCs for HCPCS codes describing skin substitute products organized by clinical and resource similarity and by their FDA regulatory pathway. The proposed APCs include APC 6000 (PMA Skin Substitute Products), APC 6001 (510(k) Skin Substitute Products), and APC 6002 (361 HCT/P Skin Substitute Products) with an initial payment rate of $125.38 for each of the new proposed APCs.

Trinity Health is concerned that the flat rate reimbursement proposal may negatively impact provider choices away from high-cost, innovative and clinically effective products to less costly, less clinically effective products. **We encourage CMS to analyze cost data, WAC and ASP and update OPPS reimbursement rates for APCs 6001, 6002, and 6003 quarterly throughout CY2026 to reflect differences in costs in a timely fashion and to mitigate clinical practice shifts due to inadequate reimbursement for high-cost, highly effective products**.

We also note that suspicious billing practices could cause significantly inaccurate and inequitable payment and repayment obligations in the Medicare Shared Savings Program if not addressed in expenditure and revenue calculations. **We encourage CMS to continue to work with ACOs to improve the process for reporting suspected fraud, waste and abuse and to explore new opportunities to deepen its partnership in promoting high-quality and efficient patient care.**

Virtual Direct Supervision of CR, ICR and PR Services and Diagnostic Services Furnished to Hospital Outpatients

In CY 2025, CMS extended virtual supervision flexibilities for CR, ICR and PR services as well as diagnostic services. Specifically, it allowed direct supervision to be furnished via two-way, audio/visual communication technology (excluding audio-only) for these services. For CY 2026, CMS proposes to permanently revise the definition of direct supervision to make permanent the availability of virtual direct supervision of CR, ICR, PR services and diagnostic services via audio-video real-time communications technology (excluding audio-only).

Trinity Health supports this provision.

Price Transparency

CMS proposes several changes to the hospital price transparency requirements. First, CMS proposes requiring several new data elements in instances when payer-specific negotiated charges are based on a percentage or algorithm. The new data elements are:

- Tenth percentile allowed amount.
- Median allowed amount.
- Ninetieth percentile allowed amount.
- Count of all allowed amounts (excluding zero-dollar claims).

CMS also proposes requiring a specific methodology, including a set lookback period, and the use of electronic data interchange 835 electronic remittance advice transaction data to calculate these values. These values would replace the "estimated allowed amount" value that was added in the final CY 2024 OPPS/ASC rule. CMS proposes requiring two new data elements for all hospital machine-readable files:

- The name of the hospital chief executive officer, president or senior official who is responsible for overseeing the machine-readable file creation and attesting to the file's completeness and accuracy.
- The hospital's National Provider Identifier(s).

The rules would also update the required affirmation statement that hospitals must attest to in their machine-readable files.

Trinity Health supports price transparency that empowers patients with up to date, meaningful cost information to make decisions about their healthcare. We are concerned that the emphasis on the machine-readable files, rather than the consumer-friendly shoppable service information, diverts attention away from the price transparency efforts that are most meaningful to patients. **As such, we continue to recommend that CMS focus on shoppable services or a price estimator tool, as a price estimator tool that can run logic based on input and give patient specific information is going to be more meaningful for patients and will do a better job providing meaningful estimates on out-of-pocket coverage.**

A recent Morning Consult survey, conducted on behalf of the AHA to assess consumer experiences with hospital pricing information, found that patients prefer price estimator tools to shoppable services spreadsheets when

estimating potential medical costs and a strong majority find them helpful in knowing where to seek medical care. Recent focus groups conducted by NORC at the University of Chicago in partnership with the AHA found similar results. During the focus groups, which included 41 commercially insured adults with varying backgrounds and experiences, participants were shown demonstrations of both hospital cost-estimator tools and shoppable services files. Compared to the spreadsheet of shoppable services files, focus group participants universally preferred the more user-friendly price estimator tools. Participants found the shoppable services files confusing and difficult to navigate. In addition, participants felt that price estimator tools more effectively provided the information they sought. **We encourage CMS to focus future efforts on the information that will best help patients understand and compare their expected costs prior to care.** The outsized focus on machine-readable file data can distract patients from the more intuitive tools that provide individualized, and therefore most accurate, estimates based on patients' cost-sharing requirements, their progress toward meeting their deductible and other pertinent information such as patient demographics.

Price transparency efforts would benefit from a comprehensive review of the numerous and sometimes conflicting requirements at both the state and federal levels. **We urge CMS to focus future efforts to reform price transparency on streamlining policies to reduce the risk of conflicting information while improving accuracy, as well as alleviating costly administrative burden for both providers and insurers.** The current landscape of pricing information is challenging for patients and employers to navigate and use effectively, and it adds excessive costs, confusion and workforce burden to the health care system. Addressing the hospital machine-readable files in isolation is misguided and only serves to add to the confusion and burden. For example, while CMS argues that the changes proposed here are intended to ensure better alignment of the hospital and insurer machine-readable files, the proposal will not align the hospital files with the current insurer files, nor has CMS proposed changes to the insurer files that would result in better alignment. Without concurrent policy changes to the insurer price transparency rule, these changes only serve to add additional burden to hospitals without achieving CMS' goal of greater alignment across hospital and insurer files.

The new data elements being proposed in this rule would increase the size of the files significantly, making them even more unwieldy and not useful for patients. Increasing the complexity and specificity of price transparency requirements increases the likelihood of errors. Due to the complexity of the current requirements, Trinity Health found it necessary to engage a third-party vendor to develop this information and as is, this vendor is unable to open MRFs in the format in which they're publicly displayed (Excel) and instead they have to open the files in a SQL database. This often means that neither Trinity Health nor our third-party vendor have visibility of the final product before publishing, which increases the likelihood of errors. As the proposed changes will only increase the size of the files, the problem would be exacerbated if finalized. **At a time when hospital resources are stretched thin, we are concerned about the additional burden and costs that the new requirements would place on hospitals, especially given the short timeline for implementation.**

The rule would also significantly increase burden on hospitals on an ongoing basis as it would add more complexity to the already complex process of annually updating our MRFs, especially if multiple contracts have changed. Further, we note that there are smaller payers that can't exchange 835 data that send us paper remittances, which makes what is being proposed more challenging and burdensome for our health system.

CMS also proposes a 12-month lookback period for the allowed amount data from the time the machine-readable file is posted, assuming the contract terms do not change over the course of that period. In instances when the contract terms do change, the lookback period would be even shorter, from the date of the contract change to the date the file is posted. While we appreciate CMS' attempt to standardize the calculation, we are concerned that this limited lookback period will not provide sufficient data for most calculations. Hospitals generally need to pull

data three months before they post it. Additionally, hospitals typically experience claims adjudication lags of several weeks, which would render data in the weeks leading up to the data pull unusable as well. Effectively, this would result in hospitals only being able to use approximately 6-8 months of allowed amounts if not less. In many instances, this will result in incredibly small counts of allowed amounts, which will not provide meaningful data due to the issues discussed previously. **To ensure hospitals have enough claims data for these analyses, we recommend CMS finalize a lookback period of at least 18 months.**

Should CMS finalize requirements for additional data elements, we recommend the agency require the inclusion of the mean rather than the median data element as proposed. The median won't illustrate where the volume of a service is and, in most cases, the mean would be the highest probability cost associated with a specific procedure/item. Alternatively, CMS could require an average as hospitals are already calculating this right now, so it would be consistent with existing work and wouldn't introduce additional calculations and increase burden to the same degree as the proposed policy. **Should they desire, CMS could take this one step further and require a mean with standard deviation to achieve a range.**

Trinity Health does not support revising the attestation on price transparency and urges CMS to maintain the current attestation language. First, the proposed attestation fails to account for the reality of hospital billing, which depends in significant part on insurer behavior and calculations and which in turn depend on a host of factors that cannot be easily calculated by a third party.

Second, the attestation in its current form sets up a trap for hospitals, and current assurances that this requirement falls outside the scope of the False Claims Act are insufficient to allay our concerns.
The proposed new attestation language would go deeper than what we include in the MRF and could be interpreted to mean that hospitals are meant to include all privately negotiated contract terms in their MRFs, which is problematic. The proposal contemplates different hospitals and health systems negotiate different agreements with different payors and publicizing those negotiated rates and frameworks or even the full text of every single one of their contracts (which would raise serious anticompetitive legal risks) would not be sufficient to enable a patient to calculate their final bill.

Critically, that bill is dependent not only on the negotiated rate for the service, but on a host of other factors, including: insurers' own proprietary algorithms, whether the service was provided in conjunction with other services, the applicability of any volume discounts or stoploss amounts, as well as other unique features of a patient's insurance plan and coordination of benefits with other payment sources. Despite these realities, the proposed attestation language would impose a standard that is impossible to fulfill, as it impossible for us to *unilaterally* provide sufficient information to enable patients to undertake these calculations on their own. The imposition of an impossible requirement by CMS would be, by definition, arbitrary and capricious, and thus unlawful. *See Alliance for Cannabis Therapeutics v. DEA*, 930 F.2d 936, 940 (D.C. Cir. 1991) ("Impossible requirements imposed by an agency are perforce unreasonable.")

Moreover, the proposed modification to the machine-readable file affirmation statement – and in particular the affirmation that the hospital "*has provided all necessary information available to the hospital for the public to be able to derive the dollar amount"* – risks ensnaring hospitals and health systems in a trap. In the first instance, the modification imposes an impossible requirement, as there is potentially limitless information available to a hospital that an individual could use to more accurately calculate a particular charge, however unreasonable to identify and provide. Particularly given the variation among insurers, among plans in a single insurer, and even among beneficiaries of a single plan, hospitals can never be entirely certain that they have provided "*all* necessary information . . . for the public to be able to derive the dollar amount." Second, as explained above, "all

necessary information available to the hospital" simply may not be sufficient to calculate the dollar amount. Given insurers' penchant for proprietary systems and calculations, there may be nuances that are not readily available to or shareable by hospitals. Though CMS contends that "strengthening this attestation . . . would better assure [CMS] and machine-readable file users that the data encoded is accurate and complete," changing the attestation does not change the reality on the ground. Instead, this proposal creates a classic "trap for the unwary." **CMS should retain the existing "good faith effort" attestation as it betters aligns with the information hospitals can be expected to provide, without raising the risk of liability for the failure to identify and provide every single piece of information that may exist**. **At the very least, the agency must account for this problem in by clarifying the reasonable scope of "all necessary information."**

For the reasons discussed above, the proposed price transparency changes are not inconsequential. **Should CMS finalize these policies as proposed, we urge the agency to extend the compliance date to 1/1/28 rather than proposed 1/1/26 to ensure that hospitals and their vendors are able to make changes to their systems and come into compliance**.

In addition, we ask that CMS provide more clarity in initial warning notices to hospitals. In many instances, delays in responding to compliance concerns are due to confusion around what issue CMS is identifying. **We encourage CMS to provide more detail about what specific issues were found during the audits, so that hospitals are able to more promptly address them.**

Quality

Cross quality changes

For the Outpatient, ASC and Rural Emergency Hospital (REH) Quality Reporting Programs (QRPs), CMS proposes to remove, beginning with the CY 2025 reporting period, three measures related to health equity that were adopted in previous rulemaking: Hospital/Facility Commitment to Health Equity, Screening for Social Drivers of Health, and Screen Positive Rate for Social Drivers of Health. CMS also proposes to remove the COVID-19 Vaccination Coverage Among Healthcare Personnel measure from all three programs beginning with the CY 2024 reporting period.

We support the removal of the COVID-19 coverage among health care personnel measure because it is very labor intensive. We do not object to the removal of the HCHE measure because structural measures are generally low-value and do not contribute to improved patient outcomes. The lack of consistency in measuring social determinants of health across sites of care and quality programs often results in duplicative screenings. However, there is still a role for the collection of information regarding how lifestyle and environmental factors influence overall health. **While a quality measure may not be best suited for the collection of this information, CMS should still encourage voluntary documentation of existing Z-codes for research purposes, including many of the research initiatives outlined in the Make America Healthy Again (MAHA) agenda.**

Hospital outpatient Quality Reporting (OQR) Program -Emergency Care Access & Timeliness eCQM

In addition to the cross-program proposals, CMS proposes adopting into the OQR program, the Emergency Care Access & Timeliness electronics clinical quality measure (eCQM) beginning with voluntary reporting for the 2027 reporting period followed by mandatory reporting with the 2028 reporting period/2030 payment period. This measure evaluates the proportion of ED encounters to meet any of the following four criteria:

- Wait time to treatment room: Patient waited more than 1 hour after ED arrival to be placed in a treatment room or dedicated area with audiovisual privacy.

- Left without being evaluated: Patient left the ED without being evaluated by a physician, advanced practice nurse, or physician assistant.
- Boarding time: Patient was boarded in the ED, for more than 4hours after a decision to admit was made.
- ED Length of Stay (LOS): Patient had an ED LOS greater than 8 hours, measured from arrival to physical departure.

Trinity Health supports removing measures that are manually abstracted and replacing them with electronic submissions and we support the removal of the two overlapping measures of Median Time from Arrival to Discharge and Left Without Being Seen. However, we have concerns with how the measure is designed, specifically with the calculation that includes the combination of the four proposed criteria and believe it could be more valuable to split these into separate measures.

In addition, we recommend that CMS push the mandatory reporting timeframe for another two years. Hospitals, and in particular smaller hospitals, need adequate time to train staff and integrate the required data elements into their EHR systems, especially if those elements required for this measure are not already being captured. This was evident during the implementation of STEM (OP-40) eCQM where early mandatory reporting created an unnecessary burden. Extending the voluntary reporting period would give hospitals the opportunity to establish best practices, identify and resolve data anomalies, and ensure more accurate meaningful reporting when the requirement becomes mandatory.

Modify Excessive Radiation Dose or Inadequate Image eCQM
CMS proposes modifications to one measure from the OQR program: Modify Excessive Radiation Dose or Inadequate Image.

- CMS is proposing to maintain voluntary reporting of the measure indefinitely and not begin mandatory reporting in response to continued feedback expressing concerns about burden and operational feasibility associated with the measure.
- The agency's proposal is to allow HOPDs more time to integrate, adequately test, and gain experience with implementing the eCQM and give CMS more time to monitor implementation progress

Trinity Health applauds CMS decision to maintain voluntary reporting of this measure indefinitely.

Ambulatory Surgery Center Quality Reporting (ASCQR) Program
CMS proposes to adopt the Patient Understanding of Key Information Related to Recovery After a Facility-Based Outpatient Procedure or Surgery, Patient Reported Outcome-Based Performance Measures (Information Transfer PRO-PM) beginning with voluntary reporting for the 2027 and 2028 reporting periods followed by mandatory reporting beginning with the 2029 reporting period/2031 payment determination.

Trinity Health does not recommend CMS finalize this measure as it will be complicated and resource intensive for ASCs to complete. In addition, a significant portion of the proposed information to be collected is included in the discharge summary and therefore is redundant.

Updates to the Extraordinary Circumstances Exception (ECE) Policies
While the process for requesting or granting an ECE remains the same as the current progress, CMS proposes to codify the following:

- That the hospital, Rural Emergency Hospital (REH), or Ambulatory Surgical Centers (ASC) would be able to request an ECE within 30 days of the date of occurrence of the extraordinary circumstance (whereas the current policy allows for 90 days).
- CMS retains the authority to grant an ECE as a form of relief at any time after the extraordinary circumstance has occurred;
- CMS will notify the requestor with a decision, in writing, via email. If granted an ECE, the written decision will state if the hospital is exempted from, or granted an extension to comply with, one or more reporting requirements.

Trinity Health strongly urges CMS to not shorten the ECE request window from 90 days to 30 days and instead align with the 60-day policy that was finalized in the CY26 IPPS rule. Past experiences with catastrophic events have shown that even a 90-day timeframe can be insufficient, given the disruptions providers face to their infrastructure and operations during such emergencies.

Hospital Star Rating
CMS proposes a two-phase change to the methodology for calculating the Overall Hospital Star Rating to emphasize hospital performance in the Safety of Care measure group. For the 2026 ratings, CMS would implement a cap at four stars for hospitals in the lowest-performing quartile in this measure group and then replace the cap starting in 2027 with a blanket one-star reduction for hospitals in that quartile.

Trinity Health strongly supports initiatives to improve patient safety and we are generally supportive of the proposed policy. However, we note that we've had experience with changes in policy that CMS ultimately ends up ending/revising because it's not working. **Therefore, before finalizing this methodology, we recommend CMS put in place additional testing so there is an opportunity for course correction prior to full implementation and public reporting.**

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