Trinity Health

September 9, 2022

Chiquita Brooks-LaSure, Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-1850

Re: CMS-1772-P; Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; Rural Emergency Hospitals: Payment Policies, Conditions of Participation, Provider Enrollment, Physician Self-Referral; New Service Category for Hospital Outpatient Department Prior Authorization Process; Overall Hospital Quality Star Rating

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

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to comment on policies proposed in CMS-1772-P. Our comments and recommendations to the Centers for Medicare and Medicaid Services (CMS) 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 115,000 colleagues and nearly 26,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 131 continuing care locations, the second largest PACE program in the country, 125 urgent care locations and many other health and well-being services. Trinity Health has 15 medical groups with 1,324 primary care providers and 4,193 specialty care providers. Based in Livonia, Michigan, its annual operating revenue is $20.2 billion with $1.2 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 2 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. Two of the 14 markets also participate in CPC+. In addition, we have had 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Unwinding the Public Health Emergency (PHE)

The flexibility provided by CMS has been integral in our ability to respond to the COVID-19 pandemic and care for our patients. This flexibility was created through a complicated patchwork of waivers, regulations, enforcement discretion and other guidance. We appreciate CMS recognizing how significant the end of the PHE is and working to develop a framework for unwinding the various authorities provided. Hospitals and physician offices developed a significant amount of system programming and logic to respond to the PHE, we urge CMS to continue to be mindful of the need for plenty of time to undo this complex system programming hospitals and physician offices have put into place throughout the PHE. Examples include automation of modifiers (e.g. CS), of condition codes (e.g., DR, 90, 91) and of charging for facility component of telehealth visit based on documentation elements.

The Administration has stated a 60-day notice will be provided prior to ending the PHE and while this notice is important and appreciated, it may not allow enough time to return to normal practices and undo the build put in place to accommodate flexibilities under the PHE. We ask that a six-month grace period be provided to allow hospitals/physician offices time to reverse all of the programming and practices that have been established over the last 2 and ½ years.

Telehealth: Hospital Services Associated with a Professional Service Provided via Telehealth Post-COVID-19 PHE

The Physician Fee Schedule proposed rule codifies authority provided by the Consolidated Appropriations Act that allows for certain key telehealth flexibilities provided by Congress to continue 151 days beyond the end of the PHE, including the originating site and geographic area flexibility. We have seen firsthand how the telehealth flexibilities provided during the COVID-19 pandemic greatly benefit patients, caregivers, and providers. Telehealth must become a routine part of patient care to maintain access and meet consumer expectations for convenient, person-centered, technology-supported care. We are committed to ensuring that all patients have the ability to use telehealth services when needed, including the most disadvantaged. We urge Congress and CMS to implement policy changes that support the permanent continuation of telehealth flexibilities to enable an efficient and equitable health care system.

Much of the telehealth clinic services provided throughout the PHE originate from hospital outpatient departments ("provider-based clinics"). With the exception of mental health services, CMS has not proposed to allow the facility component of telehealth visits to continue to be paid after the PHE ends. Not allowing a facility component associated with a professional telehealth service to continue would greatly restrict telehealth services for patients.

In the interim final rule CMS-5531-IFC, published on April 30, 2020, CMS recognized that when professional services are billed from a hospital outpatient department (HOPD) place of service, the hospital bills separately to be paid for the clinical labor, equipment, overhead, and capital to support the delivery of that professional service. Since May 2020, CMS has allowed a facility component for telehealth services that would normally have taken place in an HOPD to cover the previously noted costs incurred by the hospital. The need for recognition of facility costs and need for facility payment will not end with the PHE.

Trinity Health urges CMS and Congress work together to permanently achieve the following:

- Allow all telehealth visits to be reimbursed when originated within the patient's home or location of their choosing.
- Allow all Medicare patients access to telehealth, regardless of geographic location.

- Allow clinicians to furnish and bill with parity of payment for in-office visits across all payers and settings.
- Ensure audio-only remains a reimbursable option for physicians to care for patients who do not have audio and visual technology or capability.
- Clarify the facility component of telehealth offered in a provider-based clinic is eligible for reimbursement.
- Reimburse providers for telehealth services in home health benefits.
- Include attribution to an ACO as evidence of an existing provider/patient relationship.
- Maintain flexibility for remote-patient monitoring and reimburse for this service, including when provided through home health.
- Allow clinicians to be reimbursed for telehealth when seeing new patients or a patient not previously seen at their practice.
- Remove limitations on frequency of services.
- Advance policies that ensure access to affordable broadband, technology resources, and telehealth services for communities of color and other underserved populations.
- Allow providers to practice across states lines and at the top of their license, including medication prescription and flexibility to allow physicians to treat their patients while in a state where they may be temporarily located.

Payment Update for OPPS and ASC

CMS proposes to increase Medicare hospital OPPS and ASC rates by 2.7% compared to CY2022. This update is woefully inadequate and does not reflect the extraordinary inflationary environment and continued labor and supply cost pressures hospitals face. We urge CMS to use more updated data similar to what was used for the final IPPS rule when determining the OPPS and ASC payment amounts for CY2023 and provide a fair payment update.

Delta and Omicron surges have created a one-two punch that has crippled our health system. The recent surge in cases that fueled new Omicron variants is a warning that this public health emergency is not over. Unlike other industries, hospitals lack price elasticity and cannot simply increase prices to compensate for lost revenue and increased expenses. Not-for-profit health systems like us across the industry are in deep financial straits, as indicated by the number of bond downgrades that are occurring almost daily. Lower patient volumes and escalating labor costs due to the nursing shortage and use of expensive contract labor, combined with skyrocketing pharmaceuticals and supply expenses, have created significant financial strain on our health system. Trinity Health's cost per COVID-19 case has increased 17%, including 20% increase in labor costs from pre-pandemic levels. On a per-case basis, supply costs have increased 16%, including: Drugs 24%, Implants 6%, Other supplies 17%. There are no signs that any of these costs are returning to a lower level.

Use of 2019 Data for CY23 OPPS Rate Setting

Similar to what was finalized in the IPPS rule, CMS proposes to use CY 2021 claims data and cost data to set rates.

Trinity Health supports using CY21 data to minimize the impact of the COVID-19 pandemic.

Site Neutral Payment Policy

For CY 2023, CMS proposes to exempt rural Sole Community Hospitals (SCHs) from the site neutral policy when a clinic visit is furnished in a grandfathered (excepted) off-campus PBD of a rural SCH to help maintain access to care in rural areas.

Trinity Health supports exempting SCHs from the site neutral payment policy and recommend CMS expand the policy to exempt small rural hospitals with 100 beds or less.

In addition, Trinity Health continues to strongly oppose the site neutral payment cuts as implemented. The current policy fails to recognize several significant factors with respect to the critical role that hospital outpatient departments play in delivering services in our communities and why that often results in additional cost under OPPS. CMS has previously identified increased utilization of OPPS services but has not identified those services as unnecessary. Rather, CMS believes these services do not need to be furnished in the hospital outpatient department. Without analyzing the clinical circumstances of these cases and the acuity of the patients, CMS is not in a position to determine whether the cases were of sufficient severity and complexity that a visit in the hospital outpatient department was unwarranted compared to a physician's office.

Hospital outpatient departments are providing a hospital-level of services by meeting people—with convenient access—where they want and need to have care in their communities. Hospital outpatient departments 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. Hospital outpatient departments 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 hospital outpatient departments for critical services, particularly when it comes to the most vulnerable, sickest, and medically complex patients. Having a clear understanding of the level of acuity for patients receiving care at hospital outpatient departments is critical to continuing to move forward with such a policy decision. In addition, hospital-based ambulatory centers incur more regulatory requirements—and higher costs in meeting these regulatory requirements—compared to other outpatient settings.

340B

In June, the U.S. Supreme Court unanimously struck down CMS' policy of varying reimbursement rates for 340B hospitals. Trinity Health supports CMS' position that it "fully anticipates" reverting to its prior policy of paying Average Sales Price (ASP) plus 6% for 340B-acquired drugs in CY 2023 and we urge CMS to finalize this policy in the OPPS final rule.

CMS has also requested comments on a remedy in American Hospital Association v. Becerra. As we explain below, Trinity Health encourages CMS to adopt the following remedy including:

1. Revert to the prior policy of paying ASP plus 6% for CY 2023, regardless of whether a drug was acquired through the 340B program.
2. Promptly repay any hospital the difference between ASP plus 6% and what they were actually paid for drug claims as a result of this policy for CYs 2018-2022.
3. Hold the entire hospital field harmless for this policy for CYs 2018-2022, which means no recoupment of funds received during this period.

We strongly encourage CMS to agree to this remedy in the ongoing American Hospital Association v. Becerra litigation and to ensure that payments to hospitals are appropriately restored in the agency's CY 2023 OPPS final rule.

To correct the policy that the Supreme Court struck down, the agency should promptly repay 340B hospitals the difference between ASP plus 6% and the amount actually paid to hospitals for 340B drugs (plus applicable interest).
The survey of 340B acquisition costs initiated in CY 2020 was defective and as such cannot be used to set future payment rates, or to delay or deny repayment for CYs 2021 or 2022. That survey does not comport with the law and was never relied upon by the agency as the basis for continuation of its policy. It is not a fair, proper, or legal basis for the agency to delay or deny repayment.

CMS has suggested invoking "budget neutrality" to retrospectively recoup funds from hospitals that received them because of this policy. The agency should not penalize any hospital because of the implementation of this policy. The COVID-19 pandemic continues to cause financial challenges for hospitals. Clawing back those funds would only further put patients and communities at risk.

340B hospitals perform valuable services for low-income and rural communities but must rely on limited federal funding for support. Safety net hospitals across the country are struggling to care for their patients and communities amidst a once-in-a-century pandemic. According to the most recent report by the Medicare Payment Advisory Commission (MedPAC), hospitals' Medicare margins were negative 8.5% in 2020, even after accounting for federal relief during the pandemic.

Nothing in federal law requires — or even permits — CMS to claw back funds to achieve budget neutrality. The law governing the OPPS makes it clear that budget neutrality applies prospectively- — not retrospectively — as it addresses only future estimates and forward-looking periodic reviews. Therefore, CMS lacks the legal authority to recoup past payments to achieve budget neutrality and, to the best of our knowledge, there is no relevant instance where CMS has even tried to recoup prior OPPS payments.

For CY 2023, CMS states that it "fully anticipates" restoring payment to 340B hospitals at a rate of ASP plus 6% for separately payable drugs. In undoing the agency's unlawful policy, CMS is proposing a new budget neutrality adjustment to the OPPS conversion factor to account for this increase in payment. We have concerns, however, that the agency's calculation of this adjustment is incorrect and will result in further underpayment to all hospitals. These payments are critical for us to cover the costs associated with caring for Medicare patients. Hospitals simply cannot afford to endure further underpayments. Therefore, Trinity Health urges CMS to correct the proposed adjustment to ensure that the appropriate amount is added back into the CY 2023 OPPS conversion factor and no hospital is underpaid.

Area Wage Index

For CY 2023, CMS proposes to continue its policy of applying a 60% labor-related share to determine hospital outpatient payments. In addition, CMS proposes to adopt the final IPPS wage index policies.

Last year, Trinity Health urged CMS to consider establishing a permanent 5% floor on wage index decreases to reduce volatility in the wage index. We were pleased to see this is becoming permanent policy.

In addition, Trinity Health recognizes the need for policies to help support rural hospitals and the communities they serve. We continue to urge HHS and Congress to develop a comprehensive, long-term approach to help these facilities. As disparities among geographic regions and challenges faced by rural hospitals continue to grow, HHS should work with Congress to create a new designated pool of funding for low-wage hospitals that is not subject to budget neutrality.

Rural Sole Community Hospital Adjustment

CMS proposes to continue increasing payments to rural SCHs by 7.1% for all services paid under the OPPS, with the exception of drugs, biologicals, services paid under the pass-through policy, and items paid at charges reduced to costs.

Trinity Health supports increase payment for these facilities.

Inpatient Only (IPO) List

CMS proposes to remove ten services from the IPO list involve maxillofacial reconstruction, escharotomy and arthrodesis. In addition, the rule would add eight services to the IPO involving hernia repair, total disc arthroplasty, and mesh implantation for delayed closer defects.

Trinity Health supports the removal from the IPO list the services outlined in the proposed rule. In addition, we recommend CMS provide more clarity around appropriate settings. For example, for non-inpatient services, when is a hospital outpatient department more appropriate compared to an ASC? CMS should create ASC exclusion criteria for services removed from the IPO list and national guidelines for screening patients to determine appropriate setting.

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 override 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. 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.

PFS Proposal to Require HOPDS and ASCs to Report Discarded Amounts of Certain Single-Dose of Single-Use Package Drugs

The proposed PFS rule would implement provisions of the Infrastructure Investment and Jobs Act that requires drug manufacturers to provide a refund to CMS for certain discarded amounts from a refundable single-dose container or single-use package drug. CMS will require HOPDs and ASCs to report the JW modifier to identify discarded amounts of these drugs as well as a new modifier, JZ, in cases where no billing units of such drugs were discarded and for which the JW modifier would be required if there were discarded amounts.

Requiring reporting of the new JZ modifier will create additional administrative burden for providers. Trinity Health urges CMS to simply ensure that providers properly report the JW modifier as required and not impose additional administrative burden by finalizing the JZ modifier proposal. If onus is placed on hospitals, physician offices, and now ASCs to appropriately and completely report JW modifier as required, the JZ

modifier is not necessary. It is also essential for CMS to determine mechanisms for decreasing provider burden associated with documentation. Should CMS finalize the JZ modifier, we recommend the agency provide a 12-month runway for implementation to give providers additional time to prepare to meet the reporting requirement. Extending the implementation timeframe would be consistent with prior policy on the JW modifier, as CMS provided about 8 months for implementation of the modifier. The proposed policy is not just a simple modifier substitution-- this is different work because extra programming is required to first determine if JW is present and, if not, then apply the JZ. Depending on when the PHE expires, the 12-month extension would also provide a grace period for compliance as hospitals begin to unwind systems and other requirements that were put in place during the PHE.

Supervision by Non-physician Practitioners of Hospital and CAH Diagnostic Services Furnished to Outpatients
CMS proposes to clarify that certain non-physician practitioners (nurse practitioners, physician assistants, clinical nurse specialists and certified nurse midwifes) may supervise the performance of diagnostic tests to the extent they are authorized to do so under their scope of practice and applicable state law.

Trinity Health supports allowing providers and practitioners to practice at the top of their license.

Proposed IPPS and OPPS Payment Adjustments for Domestic NIOSH-approved Surgical N95 Respirators
The rule would make the payment adjustments for the purchase of domestically-made NIOSH surgical N95 respirators based on the estimated difference in the reasonable costs of a hospital to purchase domestic NIOSH-approved surgical N95 respirators compared to non-domestic respirators, provided as a biweekly interim lump-sum payment.

Trinity Health appreciates CMS' approach to incentivizing domestic manufacturing of N95 respirator masks and we support the concept of a payment adjustment, but we have concerns the policy as proposed would increase significantly reporting burdens on hospitals and frontline workers. This increased reporting burden would come at a time when workforce shortages have already created challenges to hospitals and health systems. Specifically, hospitals would have to differentiate domestically made respirators from non-domestically made. As such, hospitals must obtain a written statement as to manufacturing origin, as proposed by CMS, which has been certified by the manufacturer's Chief Executive Officer; the manufacturer's Chief Operating Officer; or an individual who has delegated authority to sign for, and who reports directly to, the manufacturer's CEO or COO. It is unclear how hospitals would be able to obtain such a document or if the manufacturer would provide one for the purposes of Medicare reimbursement. Certainly, requiring manufacturers to meet new labeling and reporting requirements that would be more efficient and less burdensome.

Furthermore, hospitals and health systems would be required to separately report on a new supplemental cost report form the aggregate cost and quantity of domestically made and non-domestically respirators. To do this, we'd have to devote critical staff to track, report and maintain these requirements and cost report records. Trinity Health urges CMS to work with stakeholders to determine a less burdensome method of attestation and reporting for these payment adjustments.

CMS also proposes to make the payment adjustment budget neutral under the OPPS but *not* budget neutral under the IPPS. While we support CMS' proposal to increase Medicare reimbursement for those hospitals

that purchase domestically manufactured N95 respirators, we urge CMS to make any additional payments non-budget neutral. Redistributing payments from an already underfunded system will not be of benefit to providers or to patients.

Request for Emergency Department (ED) Level National Standard

Trinity Health urges CMS to develop a national standard for ED visit guidelines for all ED levels. Hospitals are required to treat patients who present at the ED. Over the past several years a number of commercial payers have developed their own standards that are inconsistent and lead to payment denials or automatic ED level downgrades. Hospitals cannot code based on each payer's criteria as this will lead to inconsistent ED level application for the same clinical scenario.

Behavioral Health

Remote Outpatient Mental Health Services

The telehealth flexibilities afforded during the COVID-19 pandemic greatly benefitted patients, caregivers, and providers. CMS proposes to designate certain mental health services performed remotely by clinical hospital staff using telecommunications technology to beneficiaries in their homes as "covered OPD services" for which payment is made under the OPPS. Trinity Health supports establishing permanent payment for these services.

CMS seeks comment on whether requiring hospital clinical staff to be located "in" a hospital when delivering remote mental health services is overly burdensome or would disrupt care delivery models. Trinity Health encourages CMS to either remove this requirement or broaden it to include ambulatory or other clinical office locations where the providers may be located.

CMS proposes to allow hospital clinical staff to use audio-only communications technology if an individual patient is not capable of or does not wish to use two-way audio/video technology. Trinity Health supports the proposal to ensure audio-only remains a reimbursable option.

CMS proposes to require the beneficiary to receive an in-person service within six months prior to the first remote mental health service and within 12 months after each remote mental health service. These requirements may ultimately create a barrier to needed mental health services and we recommend CMS remove these criteria.

Comment Solicitation on Intensive Outpatient Mental Health Treatment, including Substance Use Disorder (SUD) Treatment Furnished by Intensive Outpatient Programs (IOPs)

CMS is seeking comment on whether intensive outpatient program services are adequately described by existing CPT codes paid under the OPPS, as well as on additional details about IOPs.

Trinity Health is committed to protecting and expanding access to high-value behavioral health services across the care continuum. We offer intensive outpatient programs at some of our regional health ministries. One program in Michigan uses a standard CPT code for group therapy (90853). The modifier of IOP is added, but this is the same code that would also be used for a standard hour group that meets once a week.

At our program in Michigan, IOP is done in an outpatient setting, three times a week, three hours a day. Currently, IOP services are facilitated by a Licensed Professional Counselor (LPC), however Medicare does not cover LPCs. This is a limitation as we cannot bill for services provided by the LPC in the IOP setting. We

are committed to providing the services a client needs, and in this case, must bill other funding which pay at a reduced rate.

Trinity Health encourages policies that allow Limited Licensed Psychologists (LLPs) and Licensed Professional Counselors (LPCs) to bill for IOP services provided. Currently, due to staff shortages, we do not have the capacity to have a licensed clinical social worker provide our IOP services. Being able to be reimbursed for an LPC providing services for Medicare clients needing IOP would increase access to care.

Quality

Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31)

CMS proposes to change the Cataracts: Improvement in Patient's Visual Function within 90 Days Following Cataract Surgery (OP-31) measure from mandatory to voluntary beginning with the CY 2027 payment determination (CY 2025 reporting period).

Trinity Health greatly appreciates CMS recognizing the current impact of COVID-19 PHE on national staffing and medical supply shortages and proposing to change the mandatory reporting to voluntary reporting beginning with the CY2027 payment determination. We support this proposal.

The OP-31 measure is burdensome. Trinity Health has evaluated various processes for collecting and reporting this measure and our discovery has identified significant burden. When CMS assesses in labor hours the burden of this measure, CMS includes only the actual reporting through the Hospital Quality Reporting application, which is 10 minutes annually. That estimate is accurate; however, that does not represent the burden of this measure as the burden is associated with gathering the data from the provider offices. Although the surgery is completed in the hospital setting, the evaluation of visual function pre- and post-surgery (within 90 days) is completed at the physician office. The hospital has no governance over the provider office practices, the visual assessment used, or whether there is an assessment completed pre- or post-surgery. We strongly encourage CMS to re-evaluate this measure regarding appropriateness of reporting. If the goal is to ensure that the visual assessment is completed by the provider, then the measure should be included in a provider-specific reporting program such as MIPS rather than a hospital reporting program such as OQR. No other OQR measure requires oversight of a data reporting process at provider offices.

Although CMS intended to reduce burden by reducing sample size, that change does not reduce the burden for hospitals that have no governance over provider office processes. The burden involves setting up consistent processes with provider offices who have no incentive to provide the data to the hospital.

Future readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) measure or another volume indicator in the Hospital OQR Program

CMS seeks comments on the future readoption of the Hospital Outpatient Volume on Selected Outpatient Surgical Procedures (OP-26) measure or another volume indicator in the Hospital OQR Program.

Trinity Health supports publicly reporting volume data by procedure type to help patients evaluate skill and experience; however, we do not support manual reporting of volume data. CMS can obtain volume data by procedure type through claims; we support adding a claims-based measure to the OQR program.

Conclusion
We appreciate CMS' ongoing efforts to improve delivery and payment systems. 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