October 15, 2023

The Honorable Michael Burgess, M.D.
U.S. House of Representatives
2161 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Drew Ferguson, IV, D.M.D
U.S. House of Representatives
2239 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Lloyd Smucker
U.S. House of Representatives
302 Cannon House Office Building
Washington, D.C. 20515

The Honorable Earl L. "Buddy" Carter
U.S. House of Representatives
432 Rayburn House Office Building
Washington, D.C. 20515

The Honorable Blake D. Moore
U.S. House of Representatives
1131 Longworth House Office Building
Washington, D.C. 20515

The Honorable Rudy Yakym III
U.S. House of Representatives
349 Cannon House Office Building
Washington, D.C. 20515

Submitted electronically via hbcr.health@mail.house.gov

Dear Representatives Burgess, Ferguson, Smucker, Carter, Moore and Yakym,

Thank you for the opportunity to provide input on how to reduce the cost of health care and improve health outcomes. Our comments 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 a not-for-profit, Catholic health care systems that is a family of 123,000 colleagues and more than 26,000 physicians and clinicians caring for diverse communities across 26 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 135 continuing care locations, the second largest PACE program in the country, 136 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, we return $1.4 billion to our communities in the form of charity care and other community benefit programs. Trinity Health is committed to serving as a critical provider in our communities and coordinating care across settings and the care continuum, with 41% of our revenue coming from Medicare and 18% from Medicaid and uninsured patients.

Trinity Health is a strong proponent of value-based care delivery. We have 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 11 markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. All of these markets participate in the "enhanced track," which qualifies as an advanced alternative payment model (APM). Two of the 14 markets also participate in CPC+. In addition, we participated 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.

Among all the players in the health care ecosystem, including insurers, drug companies, and private equity, there is enough to reimburse providers their cost of delivering care. None of us are supposed to be making double-digit profit margins. Insurers, pharmacy benefit managers (PBMS), and others in the drug industry are intermediaries sitting between patients and their treatment. We want to call attention to the practices of these businesses and organizations that run up America's health care costs.

Per a recent article featured in the Economist earlier this month, in 2022 the combined revenue of the nine biggest intermediaries was around 45% of America's health-care bill, up from 25% in 2013. Four private health insurers account for 50% of all enrolments. The biggest, UnitedHealth Group, made $324 billion in revenues last year, behind only Walmart, Amazon, Apple and ExxonMobil and its 151 million customers represent nearly half of all Americans. Four pharmacy giants generate 60% of America's drug-dispensing revenues--CVS Health alone made up a quarter of all pharmacy sales. Just three PBMs handled 80% of all prescription claims. And a whopping 92% of all drugs flow through three wholesalers. In addition, Optum Health, a subsidiary of UnitedHealth, has more doctors on its books—70,000 employed or affiliated physicians—than the largest hospital chains in the country.[1]

Meanwhile, health systems are closest to patients – we save lives and improve community health every day. Unfortunately, in today's system, the closer you get to the patient, the more money you lose. Policymakers must fix this in order to maintain and expand patient access to care.

Additionally, Trinity Health is concerned with the role private equity is playing in health care. Private equity investment in healthcare has increased significantly in recent years and researchers have found that across four areas — quality, cost to payers and patients, cost to healthcare operators, and outcomes—private equity acquisitions in health care was associated with up to a 32% increase in costs for payers and patients. Private equity ownership was also linked with mixed to harmful effects on quality, while the impact on outcomes and operator costs was inconclusive.[2]

Another study found that private equity acquisitions were associated with price increases in 8 of 10 specialties. Price hikes have been observed in specialties such as oncology, gastroenterology, and anesthesiology.[3] Private equity ownership jeopardizes patient safety by prioritizing profits, can impede care delivery through ongoing management changes and sellouts, and over-emphasizing profitable services over less profitable ones.

In the comments below, we offer the following recommendations Congress can take to promote innovation, improve quality and access, and bend the cost curve:

- Reform wasteful insurer practices, including standardizing prior authorization requirements.
- Rein in pharmaceutical and medical device costs through price negotiation.

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[1] Who Profits Most from America's Baffling Health Care System? The Economist, October 2023. Who profits most from America's baffling health-care system? (economist.com)
[2] Private equity leads to higher costs for patients and payers, Becker's Healthcare, Private equity leads to higher costs for patients, payers: Study (beckershospitalreview.com)
[3] Private Equity Investors Raising U.S. Medical Prices, Study Says, Washington Post, July 2023 Private equity firms are buying up physician practices and raising prices - The Washington Post

- Support a continued emphasis on movement to value and innovative care coordination by passing the bipartisan Value in Health Care Act (H.R. 5013) and additional policies that advance alternative payment models.
- Advance legislation that would reform the Stark and anti-kickback statute policies.
- Permanently extend telehealth flexibilities with appropriate guardrails to allow providers to continue to furnish services effectively and efficiently to patients remotely.
- Create standardized reimbursement structures and elevate the unique professional roles of community health workers (CHWs).
- Expand access to affordable housing by passing the bipartisan Affordable Housing Credit Improvement Act (H.R. 3238) and support programs for the homeless like street medicine.
- Increase access to healthy, affordable food through Food is Medicine programs.

Below are detailed recommendations for actions Congress can take to improve outcomes while reducing health care costs.

I. Regulatory, statutory, or implementation barriers that could be addressed to reduce health care spending

Reform Wasteful Insurer Practices
An extraordinary amount of waste is introduced into our nation's health system---which thereby increases costs— through commercial insurance practices that are aimed at reducing payment to or avoiding paying providers for care delivered to patients. Prior authorization is just one example of a widely used practice by health insurers that results in delayed patient care, delayed discharge to a setting with more specialized care, and impacts patient safety. Such utilization and payment tactics drive our nation's health care costs up and add burden to the health care system.

Furthering a concerning trend, insurers are now using algorithms and artificial intelligence to approve or deny claims. In March, ProPublica reported that over a period of two months Cigna used a computer algorithm to review more than 300,000 claims with Cigna doctors spending an average of 1.2 seconds on each case. This is nowhere near enough time with each claim to ensure patients receive medically necessary care, which threatened patients' health and care outcomes.

Legislators must provide oversight to ensure commercial insurance plan practices are fair, efficient and improve patient health outcomes. Specifically, Trinity Health recommends Congress:

1. Standardize the prior authorization requirements and processes by:
   - Setting standard thresholds for prior authorization.
   - Standardizing the format for communicating services subject to prior authorization.
   - Standardizing the format and content for prior authorization requests and responses.
   - Requiring 24/7 prior authorization capabilities by insurers.
   - Establishing standard timelines for responses by insurers.
   - Requiring full and complete denials in writing.
   - Standardizing appeals process with opportunity for external review.

2. Increase oversight of insurers to stop inappropriate payment delays and denials by:
   - Setting standard thresholds for payment denials.

- Implementing financial penalties for inappropriate denials.
- Testing provider network adequacy.
- Publishing performance data to compare insurers.
- Increasing frequency of insurer audits.
- Increasing oversight to determine insurers that are exceeding established standard performance.
- Imposing penalties for insurers not in compliance with standard performance thresholds.
- Requiring insurer policies and utilization management programs to be standardized and transparent, including information required from providers.
- Requiring insurers to appropriately reimburse for sepsis in a manner consistent with the CMS quality measure.

As a result of egregious insurer practices, Trinity Health experiences a cost of $10 million per month in administrative burden associated with commercial plan denials with 8% to 10% of Trinity Health's hospital encounters being routinely denied on first submission.

A survey by the American Medical Association of more than 1,000 physicians found that more than one-third (34%) of physicians reported that prior authorization led to a serious adverse event, such as hospitalization, disability, or even death, for a patient in their care. Also, more than nine in ten physicians (94%) reported care delays while waiting for health insurers to authorize necessary care, and more than four in five physicians (82%) said patients abandon treatment due to authorization struggles with health insurers.[4]

In addition, there is significant industry variation in submission processes, standard treatments, documentation requirements and definitions of medically necessary care. Further, some insurers require calls with the clinical team, often referred to as "peer-to-peer", increasing the burden to short-staffed providers. As a result, patients may wait days for medically necessary procedures, treatments or prescriptions.

A 2022 report by the Department of Health and Human Services Office of Inspector General concluded Medicare Advantage plans have a pattern of denying prior authorization and payment requests that meet Medicare coverage and billing rules. The report also affirms the findings of the Centers for Medicare and Medicaid Services' (CMS) annual audits of Medicare Advantage plans and highlights "widespread and persistent problems related to inappropriate denials of services and payment."[5]

Problematic reimbursement/coverage, delays and denials include:
- Excessive, unreasonable requests for documentation (insurers are not always clear or transparent about what documentation is required when initial claims are filed).
- Failure to provide prior authorization when necessary to prevent harm and care for patient, leading to delays in care.
- Observation status and short-stay denials even when clinical indicators meet standards for inpatient level of care.
- Reimbursement for sepsis that is inconsistent with standard coding and diagnosis so as to not reimburse for early-stage care.

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[4] American Medical Association, 2023 https://www.ama-assn.org/practice-management/prior-authorization/1-3-doctors-has-seen-prior-auth-lead-serious-adverse-event.
[5] HHS OIG, Some Medicare Advantage Organization Denials or Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care, 2022 https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

- Site of service exclusions for coverage of emergency care and diagnostic testing.
- Inaccurate enrollment files based on payer error.
- Utilization management and implementation of new policies to delay payment.

As insurers experience record profits, we are making difficult decisions on how to further lower costs, keep our teams staffed, and keep care accessible and equitable. Last year, the country's six largest health insurance companies made profits of $41.5 Billion. Meanwhile:

- The average family's premium has increased 20% over the past five years.[6]
- Increases in costs were projected to be $135B in 2022 alone for health care systems, including a $86B rise in labor costs.[7]

We must note there are some examples of member-centered health insurers that use fair practices. The Medicare Advantage plan managed by Trinity Health, MediGold, plays a vital role in our integrated delivery network and provides key care coordination for our patients. MediGold utilizes industry standard and transparent guidelines for many decisions on precertification and other authorization approval processes, removing ambiguity of guidelines for providers. Consistent, transparent, industry standard practices are best for patients, providers and taxpayers.

Rein in Pharmaceutical and Medical Device Costs
Americans pay much higher prices for prescription drugs compared to other industrialized countries. Most Americans—79 percent—consider U.S. prescription drug prices to be unreasonable, with almost 3 in 10 reporting they go without prescribed medications because of cost.[8] Since 2019, Trinity Health's cost for drugs required to treat our patients have increased 24%.

Related, the cost of medical devices have also increase and per the Medicare Payment Advisory Commission (MedPAC), large medical device companies typically have profits of 20%-30%.[9] The costs of these devices make it more expensive for hospitals to treat patients.

Trinity Health supports the Federal government negotiating drug pricing and urges Congress to extend this negotiating ability to medical device companies.

Reform Stark and Ant-Kickback Requirements
To better enable innovations in health care that would improve health outcomes and decrease costs—such as the alternative payment models discussed above—Congress should act to reform Stark and anti-kickback laws to foster arrangements that promote care coordination and advance the delivery of value-based care, while also protecting against harms caused by fraud and abuse. Action by Congress will empower CMS to provide additional guidance and support to healthcare providers who are involved in innovation.

The Stark and anti-kickback statutes and regulations continue to pose barriers to innovative arrangements among healthcare providers and suppliers and undue burden on the healthcare industry generally as it strives to

[6] https://www.kff.org/report-section/ehbs-2022-summary-of-findings/
[7] Kaufman Hall Report PowerPoint Presentation (aha.org) (2022)
[8] Government Related or Negotiated Drug Prices, Brookings, August 2021. https://www.brookings.edu/articles/government-regulated-or-negotiated-drug-prices-key-design-considerations/
[9] An Overview of the Medical Device Industry, MedPAC. jun17_ch7.pdf (medpac.gov)

improve the quality and value of healthcare delivery for patients. Agencies are constrained by the language in these laws in providing guidance permitting innovation.

These laws were enacted many years ago to address issues for a different healthcare delivery system where providers of services and other stakeholders could "profit" from overutilization of services. Today, with alternative payment models, there are new models of health care delivery that encourage value and emphasize care coordination to increase both the quality and efficiency in the delivery of services to patients. Existing safe harbors and exceptions are not designed to accommodate innovative arrangements used in new models of care delivery. The regulations and guidance that do apply fail to address specific issues raised under these arrangements or do not afford adequate protection from liability.

Stark and anti-kickback reform by Congress is necessary so that the health care system can innovate care. Modernizing these statutes will also provide a valuable tool to constrain healthcare cost escalation. Specifically, Trinity Health recommends Congress amend Stark and antikickback statue to:
- Expressly provide that care coordination is not remuneration.
- Expressly provide that housing, food, and transportation provided to existing or prospective patients is not an inducement.
- Permit compensation to a healthcare provider for reducing costs of the patient's episode of care, including the distribution of actual or projected savings amounts.
- Permit limited spending by healthcare providers to address social determinants of health -- factors that affect people's health, well-being, and quality of life.

Make Telehealth Flexibilities Permanent
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. Trinity Health is committed to ensuring that all patients have the ability to use telehealth services when needed, including the most disadvantaged. We urge Congress to implement policy changes that support the permanent continuation of telehealth flexibilities to enable an efficient health care system.

Specifically, Trinity Health urges Congress enact legislation 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.
- Allow coverage of the facility component of telehealth offered in a provider-based clinic.
- 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.

II. Efforts to promote and incorporate innovation into programs like Medicare to reduce health care spending and improve patient outcomes

Advance Alternative Payment Arrangements

Trinity Health is a leading health system implementing value-based care, with nearly $11 billion in cost of care accountability for approximately 2 million patients. We're proud of what we've done to demonstrate what a health system can do when partnering with clinicians to create better health outcomes at a lower cost for patients and the members we serve. Since 2014, Trinity Health's ACO programs have generated more than $450M in savings for CMS.

Trinity Health strongly believes alternative payment models (APMs) are effective at improving quality of care for patients while lowering costs. Value-based care aims to improve quality, outcomes and population health—while lowering costs—and can be a central driver in the delivery of people-centered care. Value-based care models engage providers to consider the whole person—including clinical needs and social supports—by linking payment to the quality and outcomes of services delivered. In addition, value-based care can reduce administrative waste by putting the decision-making into the hands of providers.

Value-Based Payment Models – Increasing Flexibility and Accountability to Support Person-Centered Care

Fee for Service + Payment Tied to Quality	Fee for Service + Risk for Quality & Cost	Total Cost of Care
• Care management fees • Pay for reporting • Pay for performance	• Shared savings with downside risk • Episode-based payment	• Global budget • Capitated payments

Provider Accountability for Quality, Patient Outcomes, Costs

In addition, these arrangements drive new sources of revenue and important pathways to develop innovative and community-based services that serve our patients. Examples of these services range from programs to reduce health risks (such as preventative and supportive programs for diabetes prevention and treatment) to those that address patient social needs (transportation, housing, employment, food security, nutrition, etc.) and community-level social influencers of health. These innovative services improve the overall health of patients, reducing unnecessary or avoidable hospital and emergency department visits as well as the overall cost of health care in the communities we serve.

The path to improving health outcomes and bending the cost curve is to encourage the movement of all alternative payment models, including those through Medicare Advantage, to provider systems in established

accountable care organizations (ACOs) that have proven their ability to manage total cost of care and outcomes, such as Trinity Health. We urge Congress to work with CMS to develop total cost of care opportunities for providers like us who are able capable of delivering quality care and outcomes while bending the cost curve. Trinity Health strongly believes this is a better alternative to handing it over to commercial payers—public companies who maximize their profitability and restrict access to services by abusing utilization management programs, such as prior authorization, change health plan coverage in the middle of a contract year, implement aggressive risk scoring and coverage denials.

Congress and CMS must incentivize providers and commercial payers to enter into risk-based, sustainable alternative payment models, including developing robust APMs with the opportunity for providers to contract directly with states. In addition, policymakers should directly incentivize commercial payer participation in population-based, premium-based advanced APMs that create new opportunities for patients and providers to benefit from improvements in quality and affordability. We recommend Congress pass legislation that would:

- Design population-based payment models that support care coordination and hold providers accountable for total cost of care and outcomes.
- Design models with different levels of accountability or risk to allow providers with varying experience with value-based care arrangements – small, rural, and safety net providers, including critical access hospitals – to participate.
- Ensure models targeting rural providers account for challenges unique to rural settings.
- Advance models that hold providers accountable for outcomes with meaningful, uniform quality and performance measures.
- Require federal and commercial payers to provide access to all administrative claims data to health care providers.

As part of this work, we urge Congress to pass the Value in Health Care Act (H.R. 5013), which would:
- Extend value-based care incentives and ensure that qualifying thresholds remain attainable for clinicians.
- Remove barriers to participation in value-based care models, such as eliminating regulatory burdens for clinicians and improving financial methodologies.
- Evaluate parity between APMs and Medicare Advantage requirements and program flexibility.
- Support continued innovation in the Medicare Shared Savings Program (MSSP) by encouraging CMS to establish a voluntary full risk track.

For additional value-based care recommendations, view our policy card, Value-Based Care: Driving Health System Transformation.

III. *Examples of evidence-based, cost-effective preventive health measures or interventions that can reduce long term health costs*

While it is widely recognized that addressing patient social needs is necessary to achieving the Triple Aim (better health, better care, lower costs), the prevailing infrastructure and distribution of resources in health care delivery systems—largely driven by fee-for-service reimbursement models and outmoded organizational culture—has not yet evolved to meaningfully integrate patient social needs into care delivery.

Invest in Community Health Workers

Professionals who can bill for services such as physicians, advanced practice providers, nurses, physical therapists and the like, are not adequately trained to identify and address patients' social needs, nor would it be top-of-license practice for them to do so. The work of professionals who are skilled in this area, such as Community Health Workers (CHWs), is not billable in most cases. Creating standardized reimbursement structures and elevating the unique professional roles of CHWs would make it possible to help meet patients' social needs in collaboration with their community partners.

Trinity Health has standardized annual social needs screening for all patients and is building CHW Hubs in each of our local health systems. These hubs are staffed by trained and certified CHWs, collaborating with both clinical care teams and local community-based organizations (CBOs) to receive referrals for patients with positive social needs screenings and use our cloud-based Community Resource Directory, powered by Findhelp, to meet these needs. We have begun incorporating CHWs into care models for our Medicare Accountable Care Organization (ACO) attributed lives, however, in most places this Medicare-focused approach limits our capacity to focus on patients most likely to have unmet social needs: those on Medicaid (unless the health system has a value-based contract with a Medicaid Managed Care Organization or patients are dually-enrolled in Medicaid) and those who are uninsured (who will not fall into any ACO's population of attributed lives).

Access to Affordable, Stable Housing

Growing evidence shows that housing stability and location can significantly affect health care costs, access and outcomes. Providing access to stable housing and housing supports can improve one's health and reduce health care costs. As an example, within a population of nearly 10,000 people with unstable housing in Oregon, the provision of affordable housing decreased Medicaid expenditures by 12 percent. At the same time, use of outpatient primary care increased by 20 percent and emergency department use declined by 18 percent for this group.[10] We encourage Congress to strengthen and expand tax incentives, like the Low-Income Housing Tax Credit, that support private investment in the production and preservation of affordable housing.

Street Medicine Programs

Street medicine programs are mobile units that provide primary care services to patients that have barriers accessing care, including those experiencing homelessness. Services include behavioral health services, vaccinations, health screenings, identifying risks for conditions such as hypertension, diabetes, and cancer, identifying and addressing barriers to accessible health care, and education resources on prevention. Several Trinity Health hospitals have strong street medicine programs, including Mount Carmel in Ohio, Mercy Care in Georgia, and Mercy One in Iowa. Congress should support the development of street medicine programs that provide health and social services to individuals experiencing unsheltered homelessness.

Integrating Food is Medicine into Primary Care

Food is Medicine refers to a spectrum of programs, services, and other interventions that recognize the critical link between nutrition and health. These services include the provision of food or tailored food assistance (vouchers for produce, etc.) and link to the health care system. Policymakers, health care providers, and social service organizations have begun to recognize that connecting people with complex health conditions to Food is Medicine interventions is an effective and low-cost strategy to improve health outcomes, decrease utilization of

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[10] Taylor, L. (June 2018). Housing and Health: An Overview of the literature. Health Affairs. Housing And Health: An Overview Of The Literature | Health Affairs.

expensive health services, and enhance patient quality of life.[11] Congress should incentivize reimbursement for evidence-based community nutrition, produce prescriptions, or medically-tailored meal programs in state Medicaid plans and managed care contracts.

Conclusion

Trinity Health appreciates the opportunity to share our thoughts on how to reduce the cost of health care and improve outcomes. We are passionate about improving health and accessibility for our communities and would gladly serve as a resource to the task force. Please contact Maggie Randolph at margaret.randolph@trinity-health.org if you would like more information.

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[11] Center for Health Law and Policy Innovation at Harvard Law School. (December 2020). "Food is Medicine: Peer-Reviewed Research in the U.S." https://chlpi.org/wp-content/uploads/2013/12/Food-is-Medicine_Peer-Reviewed-Research-in-the-U.S.1.pdf.