



February 10, 2023

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

Re: Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, Medicare Parts A, B, C, and D Overpayment Provisions of the Affordable Care Act and Programs of All-Inclusive Care for the Elderly; Health Information Technology Standards and Implementation Specifications

Submitted electronically via [www.regulations.gov](http://www.regulations.gov)

Dear Administrator Brooks-LaSure,

Trinity Health appreciates the opportunity to respond to the policies set forth in CMS-4201\_P. Our comments and recommendations reflect a strong interest in public policies that support better health, better care, and lower costs to ensure affordable, high quality, and people-centered care for all.

Trinity Health is one of the largest not-for-profit, Catholic health care systems in the nation. It is a family of 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, its annual operating revenue is \$21.5 billion with \$1.4 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. All of these markets participated in the “enhanced track”, which qualifies as an advanced alternative payment model (AAPM). Two of the 14 markets also participate in CPC+. In addition, we have participated since 2014 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, the Medicare Advantage (MA) plan managed by Trinity Health, MediGold, plays a vital role in our integrated delivery network and provides key care coordination for our patients. Over fifty-percent (50%) of

MediGold contracts are value-based agreements. MediGold utilizes industry standard and transparent guidelines for many decisions on precertification and other authorization approval processes, removing ambiguity of guidelines for providers. At MediGold, our utilization management nurses work with members and providers to coordinate care for beneficiaries identifying the beneficiary needs and working with providers to provide the needed care.

**We applaud CMS for the proposals outlined in the rule as many are consistent with comments we made in response to CMS RFIs [here](#) and [here](#).**

**Trinity Health continues to recommend that CMS take steps to incentivize MA plans to move more aggressively toward value-based care.** Based on our experience, we believe that CMS should require or incentivize MA plans to adopt value-based contracting arrangements and participate in total cost of care accountability models with providers. It's important to understand the variances in current MA value-based care models by payers to remove the inherent disadvantages to providers by normalizing for factors that work against value-based arrangements with providers – (1) the administrative efficiencies or lack thereof, (2) margin expectations of health plans/MA organizations, (3) investments made by MA organizations in membership growth by enhancing benefits, (4) bonus payment differences plan to plan for measures that providers do not control.

**Further, CMS can and should align policies across MA and Medicare FFS value-based payment models as this will support access to value-based care that aims to improve outcomes and reduce costs.** More specifically, we recommend CMS align ACO and Medicare Advantage program requirements/flexibilities including benchmarks, risk adjustment, and the ability to offer supplemental benefits. Our current experience with MA value-based payment arrangements are mixed and mostly negative because MA organizations retain majority of the healthcare dividend that providers generate through not so favorable contract terms with provider, variances in value based care models and importantly the financial impact because of the factors described above.

### **Prior Authorization**

The rule proposes significant changes for Medicare Advantage Organizations (MAOs) prior authorizations, including: requiring MAOs to follow coverage standards for Medicare FFS and that prior authorization may only be used to confirm the presence of diagnoses or other medical criteria that are the basis for coverage determinations for the specific item or service to ensure basic benefits are medically necessary based on newly specified standards or to ensure that the furnishing of supplemental benefits is clinically appropriate.

**Trinity Health supports proposed changes to MAO prior authorization, as it has been our experience that many MAOs unfairly use utilization management techniques to delay critical care.** This includes prior authorization, certifications, and medical necessity reviews that lead to unnecessary claim denials. **We are opposed to MAOs providing less services compared to Medicare FFS, but want to ensure the final rule allows MAOs to provide services “in addition to” what would be provided under Medicare FFS if determined a beneficiary would benefit.** For example, vision, dental and transportation benefits.

**We applaud the proposal that would establish that if a plan approves the furnishing of a service through an advance determination of coverage, it may not deny coverage later on the basis of a lack of medical necessity, as this practice is incredibly problematic.**

The proposed rule would also limit an MAOs' discretion to require use of alternate services or settings when a contracted provider has ordered or requested Medicare covered items or services. Therefore, the MAO may

only deny coverage of the services or setting because the ordered services fail to meet the regulatory criteria. **Trinity Health supports requiring MAOs to provide necessary care in the most appropriate setting and not creating barriers to needed services. We urge CMS to ensure there are guardrails that would not impede opportunities for effective clinical discussions/work that occur through clinically coordinated care and in alternative payment models that may identify a better treatment option or setting for a patient. For example, requiring MAOs to follow FFS Medicare, but clarifying in the final regulation that providers can appropriately manage care within their network.** A collaborative framework must exist in these models that allows clinicians to identify how to get a patient to the less restrictive site of care that is appropriate for their needs. There are times when several sites of care may be appropriate, but the highest level option may not be what is best for the patient. For example, when a patient might qualify for both skilled nursing in a facility and at home but receiving services at home will allow them to recover sooner and more comfortably. Therefore, we would want to discharge the patient home rather than to a SNF simply because they meet SNF qualifications.

**Further, Trinity Health commends CMS for the significant steps it has taken in this proposed rule to address concerns regarding MA beneficiary access to medically necessary post-acute care (PAC) services.** Institutional PAC providers, including inpatient rehabilitation hospitals and units (IRFs), long-term care hospitals (LTCHs), skilled nursing facilities (SNFs) and home health agencies (HHAs) play a vital role for recovering Medicare beneficiaries. These providers work to restore function and allow beneficiaries to return to their lives after a serious illness or injury, usually after an acute care hospitalization. However, MA beneficiaries are frequently denied access to these covered services or suffer long delays in receiving authorization for transfer to an appropriate PAC facility. This harms patients who are robbed of specialized rehabilitation care to optimize their chances of recovery, exacerbates capacity issues at general acute care hospitals and saddles health care workers with time consuming administrative appeals processes to get patients what they need.

Accordingly, CMS' proposed modifications and additions will help ensure MAOs utilize proper criteria when evaluating requests for PAC services, that MAOs use prior authorization in an appropriate manner, and that the need for repeated prior authorization requests do not disrupt patient care and unduly burden providers. These updates are especially critical for PAC services, which the HHS-OIG report highlighted as one of the top service categories experiencing inappropriate denials for covered services. In addition, to shore up the protections proposed in this rule and to ensure the availability of appropriate PAC services in MAO networks, **we recommend that CMS add a requirement that IRFs, LTCHs and HHAs be explicitly added to MA network adequacy requirements.**

If finalized, CMS would require health care professional conducting a medical necessity review for a plan needs to have expertise in the field of medicine appropriate for the item or service before plan would be allowed to issue any denial or adverse determinations. Trinity Health appreciates the proposed rule notes that MAOs "will have discretion to determine on a case-by-case basis what constitutes appropriate expertise based on the services being requested and relevant aspects of the enrollee's health condition." **We recommend CMS reiterate this flexibility in the final rule as there are many medical specialties and having the same type of specialist review each case could be very onerous. In addition, we urge CMS develop a reasonableness standard to ensure the proposal is balanced and is sensitive to the clinical workforce shortage that could be impacted by an overly decisive policy.** For example, an Internal Medicine or Family Practice Physician who has experience caring for the elderly and disabled would be an appropriate health care professional who could review medical necessity.

In the face of compelling evidence that certain MAOs have historically circumvented federal rules in applying overly restrictive medical necessity criteria, we recommend **that CMS adopt more specific language regarding the Traditional Medicare rules that MAOs are required to follow.** For example, we interpret that the reiteration of inpatient admissions as a basic benefit and the requirement that MAOs cover basic benefits in a fashion that is no more restrictive than Traditional Medicare means that MAOs must follow the Two-Midnight rule and adhere to the Inpatient Only List. This would effectively prevent MAOs from downgrading inpatient hospital stays that exceed two midnights to observation status as raised in the preceding examples — a practice that effectively applies a more restrictive set of criteria to an inpatient admission. **We urge CMS to explicitly state that MAOs must follow the Two-Midnight rule, for example, as opposed to leaving this to an interpretation of logic.**

There is significant industry variation in terms of when prior authorization is necessary, submission processes, standard treatments, documentation requirements and definitions of medically necessary care. As a result, patients may wait days for medically necessary procedures, treatments or prescriptions. This can not only impact care, but may also create anxiety for the patient while burdening the clinical team and their staff.

On claims denials, from July 1, 2021 to April 30, 2022 Managed Care MA Plans had denied over \$1.12 billion on 147,000 claims across Trinity Health facilities, compared to traditional Medicare denials of \$0.38 billion on 112,000 claims, despite gross revenue being just about equal between the two. This high rate of denials both affects patients and causes significant administrative burden. In Trinity Health's experience:

- Administrative burden associated with commercial plan denials costs Trinity Health \$10 million per month.
- 8 to 10% of Trinity Health's total hospital encounters are routinely denied on first submission.
- A requirement to submit excessive documentation is the top reason for payment denial. However, documentation denials are almost always eventually approved.
- Clinical denials require an arduous appeals process that often includes peer-to-peer interactions with clinical staff, with an eventual approval 55 to 65% of the time.

Trinity Health has experienced the following excessive utilization management and medical necessity review practices that delay care, create uncertainty for patients, and cause unnecessary administrative burden:

- 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 patients, leading to delays in care.
- Observation status and short-stay denials even when clinical indicators meet standards for care.
- Reimbursement for sepsis that is inconsistent with standard coding and diagnosis so as to not reimburse for early-stage care.
- 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.

Inappropriate prior authorization and payment denials restrict or delay patient access to care and contribute to health care provider burn out. Further, such utilization and payment tactics drive our nation's health care costs up and add burden to the health care system. CMS could take the following steps to reduce the impact of improper

utilization management techniques by MA plans and other plans that the agency oversees, while still ensuring program integrity.

***CMS should standardize prior authorization requirements and processes across its programs:***

- Set standard thresholds for prior authorization.
- Standardize the format for communicating services subject to prior authorization.
- Standardize the format and content for prior authorization requests and responses.
- Require 24/7 prior authorization capabilities by insurers.
- Establish standard timelines for responses by insurers.
- Require full and complete denials in writing.
- Standardize appeals process with opportunity for external review performed by an independent entity with no relationship to the MA plan or provider.

***CMS should increase oversight of insurers to stop inappropriate payment delays and denials:***

- Set standard thresholds for payment denials.
- Implement financial penalties for inappropriate denials.
- Test provider network adequacy.
- Publish performance data to compare insurers.
- Increase frequency of insurer audits.
- Increase oversight to determine insurers that are exceeding established standard performance.
- Impose penalties for insurers not in compliance with standard performance thresholds.
- Require insurer policies and utilization management programs to be standardized, such as use of Milliman Care Guidelines, and transparent, including information required from providers.
- Require inpatient coverage for admissions that meet the Two Midnight Rule.
- Require outpatient coverage and payment for admissions that don't meet the Two Midnight Rule.
- Extend direct oversight over MA Plan subcontractors that perform administrative functions on behalf of MA Plans.
- Require insurers to appropriately reimburse for sepsis in a manner consistent with the CMS quality measure.

Consistent and transparent industry standard practices are best for patients, providers, and taxpayers.

**Marketing Requirements**

CMS proposes more than 20 distinct changes to the marketing regulations, noting that it has seen an increase in beneficiary complaints over the past several years.

**Trinity Health supports all of the marketing policies in the proposed rule, as it will end certain misleading marketing strategies.** We note that MediGold does not do any of the negative marketing described in the rule that would be addressed by these provisions.

**Star Ratings**

*Weighting of Patient Experience Measures*

CMS proposes to reverse a policy in the MA and Part D CY 2020 Final Rule that served to increase the weight of the patient experience/complaints and access measures from 2 (which was established in the CY 2018 Final

Rule) to 4. CMS notes that when weighted at 4, CAHPS accounts for 58 percent of any MA plan's Star Rating. When weighted at 2, CAHPS will account for 41 percent of the total rating.

Trinity Health recognizes the importance of establishing strong rationale for how measure weights are established. **We recommend CMS align CAHPS with the weighting of outcome measures in the Star Ratings program, which are currently weighted at 3.** MedPAC has recommended in previous comments that there should be proportionate weighting between patient experience measures relative to outcome measures, to avoid creating an imbalance between the two most important measure groupings. In addition, we recommend CMS refrain from implementing significant year-over-year changes in the Star Ratings measure weights and methodology, and that CMS provide greater consistency and predictability in the ratings methodology calculations.

#### *Health Equity Index*

To encourage health plans to improve performance for patients with certain social risk factors, CMS would replace its current reward factor for consistently high star ratings performance with a new health equity index (HEI) reward. The HEI reward would be calculated by assessing each plan's performance on selected measures for enrollees that are dually eligible for Medicare and Medicaid, receive the Part D Low Income Subsidy (LIS) or are disabled.

**Trinity Health supports incentivizing plans to focus on achieving health equity for enrollees. However, we are concerned that the Health Equity Index as proposed may undermine the Administration's health equity goals due to the significant negative consequences of the multiplier on a health plan's Star Rating.** CMS' proposal would change the current reward factor so that it becomes a two-sided, net-zero approach that looks at each measure and breaks contracts into thirds, with the top third of contracts receiving 1 point, the middle third of contracts receiving 0 points, and the bottom third of contracts receiving -1 point. **As proposed, this could have unintended negative consequences including:**

1. **Working against health equity goals would lower Star Ratings, thereby reducing revenue available to help beneficiaries:** Star Ratings help generate the revenue for supplemental benefits — such as medically tailored meals, transportation, and in-home supports — that go even farther to address health-related social needs. CMS' penalties would reduce revenue for the plans that serve the beneficiaries who need these resources the most.
2. **Undermining improvements in health equity in certain contracts:** Under the proposed enrollment thresholds for beneficiaries with social risk factors, some contracts, such as Group Retiree contracts, would not have access to the HEI reward, even if they are advancing health equity. In addition, there are MAOs that do not have a significant amount of dual eligibles enrolled due to state initiatives (such as in OH). By potentially rendering these contracts as ineligible for the reward, it would be more difficult for these contracts to achieve high Star Ratings. **Any revisions to the HEI reward framework should ensure Group Retiree contracts qualify to ensure that plans working to improve health equity can appropriately achieve high Star Ratings and we urge CMS to ensure that plans aren't penalized for having a low duals volume because a state has identified a different pathway for the population.**
3. **Creating an incentive for beneficiary selection:** CMS has worked to mitigate any incentive for health plans to target or avoid cohorts of beneficiaries in its contracts. CMS' proposed "net zero" approach would incentivize selection for the purpose of maximizing the HEI reward, which would work against CMS' goal of eliminating incentives to enroll specific cohorts of beneficiaries in the risk adjustment program.

**Trinity Health recommends that CMS implement an HEI reward framework that meaningfully rewards health plans for improving health outcomes of historically marginalized populations.** Such an approach would mitigate the unintended consequences described above. Specifically, we recommend CMS implement an approach that applies to all contracts (i.e., removes enrollment thresholds) and is not two-sided. We also recommend that the HEI reward be phased in, and not immediately be a replacement for the current reward factor.

**We also support incorporating data from the Area Deprivation Index into the Health Equity Index in the short term.** CMS should also be aware of other resources for similar data, such as the Social Vulnerability Index (SVI), which ranks each census tract on 15 social factors and groups them into four themes (socioeconomic status; household composition and disability; minority status and language; and housing type and transportation).

One notable difference is that the SVI includes race as a factor, whereas the ADI does not include race or ethnicity. Each index has different strengths: the ADI is better suited for looking at social disadvantages within specific neighborhoods, whereas the SVI is better suited to assessing larger geographic regions. **Depending on the data needed for the health equity index calculations, we urge CMS to look at other existing methods to determine which is best suited for the task.**

Finally, CMS has made significant changes to the Star Ratings program methodology over the past several rulemaking cycles, including the proposed shift to the current measure weighting policy for the 2023 Star Ratings. Significant methodological changes year-over-year make it difficult for payers and providers to make stable, strategic investments in targeted quality improvement, as CMS' incentives are frequently shifting. **We urge CMS to avoid making significant year-over-year changes to the Star Ratings until there is compelling evidence of the policy effects of the current methodology.**

### **Promoting Health Equity**

In the summer of 2020 as the impacts of COVID-19 on minority and underserved communities became clearer, Trinity Health initiated a systemwide effort led by our senior leadership, including our system CEO, to examine our role as a health system in advancing equity across all of our communities. As part of this effort, we have developed a set of principles to guide our journey to health equity, which can be found [here](#). We have engaged representatives from all of our regional health ministries to both develop our guiding principles and to implement these principles locally to reflect each community's unique strengths, challenges, and needs.

**To this end, we support proposed measures to further address health equity by including underserved groups beyond linguistically and culturally diverse populations in the cultural competency requirement to include people with disabilities, people of diverse sexual orientations, and people who live in rural areas. Trinity Health also supports the proposed requirement for MAOs to include in their directories each provider's cultural and linguistic capabilities, including American Sign Language, as well as notations for providers waived to treat patients with medications for opioid use disorder. While this may be more work for our health system to capture, its important to advance the health equity of our communities.**

### **Behavioral health**

CMS proposes several provisions that would establish standards for access to behavioral health services under MA, including expanding network adequacy requirements and adding behavioral health to the list of services for which MAOs must have programs for continuity of care and integration and services. CMS also proposes to clarify the definition of "emergency medical conditions" to include both physical and mental conditions. Behavioral health services that qualify as emergency services may not be subject to prior authorization.

Trinity Health supports expanded access to behavioral health. **Given the proposed network adequacy standards, we ask that CMS provide health plans enough time to secure contracting with behavioral health providers.**

### **Medicare Overpayment**

CMS is proposing to modify the time period for which providers must repay any identified Medicare overpayment. Under the current rule, providers and suppliers that become aware that a potential overpayment may have occurred are expected to investigate the existence of the overpayment and quantify the amount before notifying the government and returning the overpaid amounts. Only after the quantification of the overpayment (CMS allows for up to a 6-month investigative period) does the 60-day clock begin to run on returning the overpayment to the government. The proposed rule would remove this investigation period and require overpayments be reported and returned within 60 days.

**The proposal would result in an unrealistic strict 60-day timeline to return overpayments once they have been identified. This new proposed timeline will be nearly impossible to meet, subjecting organizations to unnecessary False Claims Act liability even when we are acting in good faith to comply.**

In the proposed rule, CMS does not address the inherent ambiguities and practical problems presented by the proposed definition. For example, the proposed rule does not explain how a provider or supplier would return an overpayment within 60 days if the existence of the overpayment is known but the *amount* of the overpayment remains unknown. It is not uncommon for it to take several months, if not more, for a provider or supplier to determine the amount of an overpayment.

Once we identify a potential overpayment, our compliance and revenue cycle teams conduct an extensive and rigorous audit investigation to collect facts, identify the source of the discrepancy, mitigate any continuing circumstances if the issue is ongoing, and determine exactly how much money must be returned. This requires identifying every claim that may have been overpaid by claim number, dates of service, and amount billed and paid. It also may involve complex statistical sampling followed by quality checks, as well as consultations with the Medicare Administrative Contractor. Given the six-year lookback period, moreover, in many instances claims data is already archived or stored on legacy systems and must be “restored” such that it can be queried for the unique claims at hand. And in some cases, identifying refunds involves applying different legal standards to different years of claims because Medicare rules change over time, further complicating the analysis and identification. For more information for what this process entails, please see the following example for Intensity Modulated Radiotherapy Treatment (IMRT).

#### *Overpayment Process Example: Intensity Modulated Radiotherapy Treatment (IMRT):*

Intensity Modulated Radiotherapy Treatment (IMRT) planning has complex billing rules that bundle reimbursement for several other services into the payment for IMRT planning. These services include simulations field setting, dose volume histogram creation, special dosimetry calculations and other services represented by CPT codes. Medicare Claims Processing Manual 100-04 Section 230.1 contains specific Medicare billing rules for IMRT services. The National Correct Coding Initiative (NCCI) further defines code combinations that cannot be reported together with IMRT Planning 77301. Traditional claims editing software at CMS, or that used by hospitals, cannot be programmed to capture all the component services, and prevent them from being billed with IMRT Planning CPT Code 77301, because



the component procedures are performed on different dates of service and often precede the IMRT plan completion. Several component services are also repeated during treatment but cannot be billed when performed. Documentation systems often place charges to the patients account based on the ordered service that is completed, which cannot distinguish if the service was performed for IMRT or conventional radiation treatment where charging and billing is appropriate.

In conducting reviews of IMRT planning services for potential validation of overpayment several steps must be undertaken. First, we need to identify populations of beneficiaries that received IMRT planning services. Second is to identify populations of beneficiaries that had the component services performed. Reports or queries of this complexity often require the Information Service department to write code to query institutional databases for appropriate data in discreet fields and specify the parameters and output specifications for the deliverables, which can often take weeks for turnaround. The two populations of patients were then cross matched against each other to identify potential overpayments based on charges present on encounters.

Once the population is narrowed down to potential overpayments, each account has to be investigated to determine if the charges for the component services were billed to Medicare or manually removed off the account prior to claims submission during claim reviews. Further compounding the investigation, radiation treatment accounts are billed in series format, once a month, requiring manual review and comparison of more than one account per beneficiary. Each account has to be investigated for proper billing procedures to determine if an overpayment had been received. Each medical record, line item of financial account, UB-04 and EOB had to be carefully reviewed for every beneficiary in the population to determine if overpayments were received. Previously, this portion of the review took a minimum of two months to conduct.

Once the population of accounts with overpayment are identified, all regulatory changes that have occurred for each year must be reviewed and understood, as component codes change over time. Also, status indicators for each CPT code involved must be reviewed for accurate reimbursement logic to be applied for quantification. Finally, reimbursement for each component service must be evaluated for quarterly payment rate updates and any geographic updates to base payment rates. Once those steps have occurred, overpayment amounts can be quantified for each of the accounts or services. This portion of quantification is also very time consuming.

Once quantified, a refund check must be requested from accounts payable back to the appropriate Medicare Administrative Contractor (MAC). Check requests often take weeks to complete their cycle through finance. Once a check has been written to the Medicare Administrative Contractor, a voluntary refund form is to be completed that includes the amount of refund check, the check number, and the check date. Each MAC has a different form, different address (sometimes two) for mailing the voluntary refund notification form and each MAC has varying required account details that must accompany each claim that is being refunded.

Overall, this investigation and quantification has taken approximately 5 1/2 months to complete and several additional weeks to complete having a check(s) cut, completing the voluntary refund forms, and mailing the refund to the Medicare Administrative contractor.

The existing process for identifying and repaying overpayments is working. Trinity Health has a highly effective compliance program—from 2000 to today, we have paid back more than \$100 million and have done so as soon

as amounts were identified and investigated. Significant resources and time go into identifying whether there is an overpayment, as the amount we are paid is not the same each geographic location, each fiscal year, or even month to month.

**Trinity Health urges CMS not to overcorrect due to a bad actor and allow for reasonable amount of time for providers to investigate and quantify how much is owed in any potential overpayment. For the reasons we list above, we recommend HHS withdraw this portion of the proposed rule or clarify in the final rule that providers will have “the time necessary to calculate the amount of overpayment.”**

### **Program of All-Inclusive Care for the Elderly (PACE)**

Trinity Health PACE is the largest not-for-profit PACE provider in the US, serving more than 3,300 participants in 9 states; this is evidence of our commitment to value-based care.

#### *Beneficiary Incentives*

Trinity Health PACE views the unrestricted practice of MA plans offering gift cards and monetary incentives to their members as a significant disadvantage to PACE programs both in attracting new participants and retaining existing participants. The allure of these funds is enticement enough to lure prospects and members to enroll with MA competitor plans. Despite the restrictions that MA plans put on the use of these funds, the ability to access additional funds is highly desirable to the population that we serve. Some MA plans within our provider market do not have to abide by the same restrictions that PACE programs have in regard to paying for some benefits. This inequality in regulations gives MA plans an unfair advantage. For example, an MA plan in Pennsylvania provides marketing material that shows that the plan allows their members to use their health plan rewards to pay their rent. PACE is prohibited from this type of expense. Again, giving the MA plan an unfair advantage.

While PACE can pay for other similar expenses to MA plans if the Interdisciplinary Team (IDT) determines that it is in the best interest of the participant, MA plans make these incentives available to all members. If PACE programs were to adopt a similar approach, it would come at significant financial cost to PACE and our capitated funding would not support this type of expense. We also have concerns that this type of benefit would be taxable.

**Therefore, Trinity Health PACE recommends that CMS level the playing field and give PACE the same advantages that that MA Plans have in terms of gift card use. By doing this CMS must also recognize that to be able to fairly compete, PACE capitation rates would need to adjust upward as the per member per month cost would increase. We also support increased flexibility around PACE marketing guidelines and restrictions in order to create a level playing field with MA plans and other competitors.**

#### *Contract Year Definition*

CMS is proposing a revision to the contract year definition to provide greater flexibility around scheduling PACE Organization's (POs) first trial period audit and ensure that POs have sufficient time to enroll and gain adequate program experience prior to their first trial period audit. The definition would specify that a POs initial contract year may be 19 to 30 months, as determined by CMS, but in any event will end on December 31. **Trinity Health PACE supports this proposal as it eases the POs burden and ensures the initial audit is meaningful. A longer timeframe is preferred however, we recommend 25-36 months.**

#### *Application Requirements and Notice of CMS Determination*

CMS proposes to add a paragraph in the application requirement indicating that if the State assurances document is not included or is not signed and dated by the State Administering Agency and does not include

accurate service area information and the physical address of the PACE center, the application would be deemed incomplete and invalid. **Trinity Health PACE does not support this change due to recent instances in which the state submitted inaccurate or incomplete State Assurances. This requirement would put our applications in jeopardy and delay program development.** States create their own State Assurance pages in conjunction with their CMS contact. The PACE organization is not included in this process and does not have oversight of the state's submission. In our case, one of our Requests for Additional Information (RAI) indicated that the state's assurances did not match the discussion that CMS had with that state. We were not privy to that information prior to the RAI. Implementation of this requirement would put the PO at risk for a process that they do not control. Placing the burden of consequence for an action not overseen by the PO is both unfair and unprecedented.

#### *CMS Evaluation of Applications (Past Evaluations)*

The CMS proposal that would allow them to deny an application based on the organization's past performance, which considers compliance letters received by an organization, needs further clarity. While this is intended to prevent poorly performing POs from opening other sites, **Trinity Health PACE is seeking further clarification whether this is solely tied to the fiscal soundness of the Corrective Action Plan (CAP) and does not mean six points for each Corrective Action Required (CAR).** Clarification of what audit results will be leveraged and how will self-reporting tie in. Trinity Health PACE supports the proposed exception to the policy by providing a 24-month grace period to a PACE organization that acquires an organization that would have been denied based on the above factors.

#### *Personnel Medical Clearance*

CMS proposes to require all POs to develop and implement a comprehensive medical clearance process with minimum conditions deemed acceptable to CMS requiring each member of a POs staff (employee or contractor) who has direct contact with participants to have all immunizations up to date before engaging in direct participant contact. Immunizations include, at a minimum, vaccinations identified at § 460.74, including vaccinations for COVID-19. In addition, the proposal would require the medical clearances be conducted annually (in addition to before engaging in direct participant contact) on an ongoing, not a one-time responsibility of POs. **Trinity Health PACE does not support this proposal as an annual health screen would be burdensome for organizations. No other comparable settings of care have these requirements.** While CMS would permit POs to utilize a PO employed provider, Trinity Health PACE has privacy concerns in regard to health exams of colleagues. Trinity Health PACE is also seeking clarification of the immunizations included as "up to date COVID immunizations," and if the primary series would suffice for this rule.

#### *Contracted Services*

CMS proposes to restore in the PACE regulation the list of twenty-five medical specialties commonly utilized by PACE participants consistent with the specialties previously enumerated in the original PACE protocol, adding a new requirement that a PO execute contracts with specialists prior to enrolling participants and maintain these contracts on an ongoing basis. CMS clarifies that POs may meet this requirement by contracting with a multi-specialty practice or provider. There is a new stipulation that a PO makes reasonable and timely attempts to contract with medical specialists. **Trinity Health PACE believes that these requirements could place an undue burden on PACE organizations, especially those in rural areas where there are a lack of provider types/specialty providers and/or local provider(s) refuse to contract.** Even in urban areas, there are some provider types that refuse to contract with a PO, e.g., anesthesiology, but who provide services as part of the hospital's agreement or through a single case, or non-par, agreement. POs are required to have access and provide the full benefit to which a PACE participant is entitled. **Trinity Health PACE believes that a better approach would be rather than be prescriptive about the contracting process, the focus should be on if**

**participants are being denied or not receiving medically necessary services due to a POs lack of network adequacy or management.**

*Service Delivery (Timeframes for Coordinating Necessary Care)*

CMS proposes to establish timeframes for arranging the provision of the Interdisciplinary Team (IDT) approved services for PACE participants. Specifically, POs must arrange and schedule, as expeditiously as the participant's health condition requires. For medications, no later than 24 hours after the primary care provider orders the medication. For all other (non-medication) services, no later than seven calendar days after the date the Interdisciplinary Team (IDT) or a member of the IDT first approves the services. **Trinity Health PACE believes that a maximum timeframe of 7 days would be extremely challenging for specialty items such as Power Mobility Devices, stair lifts etc. and asks CMS to reconsider this timing requirement.**

*Interdisciplinary Team (Care Coordination)*

CMS is proposing policy changes to clarify IDT responsibilities. **Trinity Health PACE recommends modifying the language that states 24 hours from the time of the participant's discharge to within 24 hours of PO being informed of participant's discharge. In addition, we do not support a 7-day timeframe to act on recommendations as it may not be possible in some circumstances.** Hospital systems vary in timeliness of providing discharge summaries and if we do not have access to their EMR system it causes delays in receiving records.

*Plan of Care*

CMS is proposing extensive changes to clarify and codify the *minimum* requirements for a participant's plan of care to further define the timeframes for care plan development and reevaluation; emphasize the ongoing responsibilities of the IDT to monitor and revise the plan of care to determine its effectiveness; and define the involvement of the participant and/or their caregiver in the plan before it is finalized. **Trinity Health PACE agrees with the timing and that acute and chronic behavioral disorders be included. Trinity Health PACE is concerned about the additional new rule requiring the plan of care to identify each intervention necessary to meet each medical, physical, emotional, and social need (except medications that may be documented elsewhere in the medical record) as this could create administrative burden in terms of a lengthy list of standard problems in each care plan.**

*Participant Rights*

**CMS proposes several changes to ensure that PACE participants understand their rights and Trinity Health PACE agrees with these changes.**

*Grievance Process*

**CMS has clarified the grievance process and Trinity Health PACE is in support of the regulation changes and clarity.**

*Service Delivery Requests*

**Trinity Health PACE is in support of the proposal.**

*Participant Notification Requirement for POs with Performance Issues or Compliance Deficiencies*

**Trinity Health PACE is in support of the proposal.**

*Maintenance of Medical Records*

CMS is proposing that POs would still be required to maintain pertinent written communications (e.g., emails, faxes, letters, etc.) from participants or other parties in their original form but would remove the requirement that these communications be stored in the participant's medical record if specific conditions are met. **Trinity Health PACE does not support this proposal as it seems unnecessary. It could cause confusion and lack continuity around storage and access to additional charts or files containing participant information.**

**Conclusion**

Thank you for the opportunity to comment. If you have any questions, please contact me at [jennifer.nading@trinity-health.org](mailto:jennifer.nading@trinity-health.org).

Sincerely,

/s/

Jennifer Nading  
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Trinity Health