



March 13, 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 and Medicaid Programs; Patient Protection and Affordable Care Act; Advancing Interoperability and Improving Prior Authorization Processes for Medicare Advantage Organizations, Medicaid Managed Care Plans, State Medicaid Agencies, Children's Health Insurance Program (CHIP) Agencies and CHIP Managed Care Entities, Issuers of Qualified Health Plans on the Federally-Facilitated Exchanges, Merit-Based Incentive Payment System (MIPS) Eligible Clinicians, and Eligible Hospitals and Critical Access Hospitals in the Medicare Promoting Interoperability Program

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—0057-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.

**Trinity Health applauds CMS for the policies outlined in the proposed rule as they will help address challenges with delayed patient care and increased provider burden and administrative costs that are associated with the existing prior authorization process. In addition, effective data sharing and system interoperability is critical to improving the provision and coordination of health care, and we support the focus CMS has placed on advancing these issues through the use of standard application programming interfaces (APIs).**

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 and the use of the identical clinical information and documentation/coding/billing systems with the same level of comprehensive clinical documentation of care and resource utilization. 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 plans that the agency oversees, while still ensuring program integrity.

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

- Set standard guidelines 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 guidelines 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 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.

### Patient Access APIs

The proposed rule would add information on prior authorization requests and decisions to the list of health information payers must give patients access to via the FHIR APIs promulgated in the May 2020 Interoperability Patient Access final rule. Payers would need to provide this information within one business day, allowing patients to track all prior authorization request.

**Trinity Health supports including prior authorization in the patient API requirements.** We are working with partners to implement the Trusted Exchange Framework and Common Agreement (TEFCA) that will standardize interoperability and security. In addition, we recommend CMS consider developing guidance, educational materials and policies that increase patient access and use of this important data, as well as awareness of the privacy and security protection their data may or may not have depending on where they share it.

### Provider Access APIs

Payers must build and maintain Provider Access APIs to enable in-network providers to access payers' information on current patients, including prior authorization requests and determinations.

**Trinity Health supports this requirement and agrees that unlike the policy published in the December 2020 Notice of Proposed Rule, patients must opt out rather than opt into the API.**

### Payer to Payer Data Exchange

Impacted payers would be required to implement and maintain a payer-to-payer data exchange using a FHIR API and a patient opt-in policy. As with the Patient Access API, the proposed Payer-to-Payer API requires sharing all data classes and data elements, adjudicated claims, and encounter data as well as the patient's prior authorization requests and decisions.

Trinity Health is concerned that CMS is not proposing to require payers to honor or review active prior authorization decisions of a former payer for a patient and this is inconsistent with policies included in the recently proposed 2024 Medicare Advantage Contract Regulation, CMS-4201-P. **We urge CMS to clarify that for beneficiaries undergoing an active course of treatment, a prior authorization approval would remain valid for an enrollee's full course of treatment.**

**In addition, we urge CMS to use the proposed APIs to capture additional coverage a patient may have.** Payers sometimes hold payment to providers for items/services until a patient answers whether they have any additional health insurance for coordination of benefits (COB). There is no data base for this information to solve the issue electronically and it often delays payment to providers or providers don't receive reimbursement at all. Having the payer and patient share this information through the API is a first step to simplifying this barrier and addressing burden associated with providers having to get in contact with patients to determine this payer requirement.

### PARDD API

CMS proposes to require impacted plans to implement and maintain a FHIR-based Prior Authorization Requirements, Documentation, and Decision (PARDD) API. The PARDD will enable providers to: 1) ascertain whether prior authorization is required for a particular item or service (excluding drugs), 2) query and identify in real time the specific prior authorization rules and documentation requirements for a

particular service, and 3) populate prior authorization forms directly from the provider's EHR or practice management system.

**Trinity Health applauds CMS for including the PARDD API requirement as it will provide transparency for a process that has historically been exceptionally burdensome and opaque.**

Historically, payers are not always clear about what documentation is required for prior authorization when initial claims are filed or require excessive documentation. Trinity Health believes the PARDD API will improve the prior authorization process.

Public Reporting

CMS proposes to require plans to report annually on aggregated metric related to prior authorization, including: 1) a list of all items/services that require prior authorization, 2) the percentage of requests that were approved or denied, and 3) the average and median time that it took between the submission of a request and a determination by the payer.

This reporting will create additional transparency in the prior authorization process, and Trinity Health recommends CMS finalize this requirement. However, we have concerns that CMS is not proposing a specific format for how payers should present the aggregated data. **Due to the importance of this data, we urge CMS to include specificity for the display of this information in the final rule to ensure it is accessible, readable, and usable.**

Request for Comment: Gold Carding

CMS seeks comment on gold carding programs in which payers relax or reduce prior authorization requirements for providers that have demonstrated a consistent pattern of compliance with payer requirements.

**Trinity Health is generally supportive of gold carding and encourages CMS to explore potential piloting/testing as this would expedite care for patients.** Given the delays in care and administrative overhead associated with the prior authorization process, gold carding could be helpful if designed properly and fairly. **We caution that requirements for gold carding programs need to be very transparent, including clear metrics for eligibility, the revalidation process, and what services/settings are eligible.** If gold carding is implemented and to eliminate any delays in care for patients, providers need to receive immediate approval from payers for gold carded services. In addition, if one of our providers receives gold carding status, it is imperative as a health system that provides coordinated care for payers to quickly authorize care at facilities we partner with.

A gold carding process that is overly granular (e.g. exempting a provider for only specific CPT codes) would be challenging, as the CPT code may change slightly during the course of care, which could cause reimbursement issues post-care. **Additionally, any gold carding program needs to be designed so that providers are exempt for an established length of time, such as one full calendar year. If a program was based simply on a rolling basis or was subject to change too frequently, it would pose additional administrative burden challenges and result in reimbursement issues.**

### New Electronic Prior Authorization Measure

CMS proposes to add a new “Electronic Prior Authorization” measure for eligible hospitals and critical access hospitals (CAHs) under the Medicare Promoting Interoperability Program and for MIPS eligible clinicians under the Promoting Interoperability performance category of the Merit-Based Incentive Payment System (MIPS).

**Trinity Health recommends CMS offer a minimum 1 year of flexibility for this measure, via an exclusion, similar to what is offered as part of the hospital 2023 measure ‘query PDMP’ such that, “EXCLUSION: Any eligible hospital or CAH for which [this measure] would impose an excessive workflow or cost burden prior to the start of the EHR reporting period they select in [program year]”. In addition, CMS should consider, and provide clarity on in the final rule, how this new measure will be prioritized with in the larger interoperability (PI) program**

### Conclusion

Trinity Health commends CMS for taking important steps to remove barriers to patient care by streamlining the prior authorization process. If you have any questions on our comments, please contact me at [jennifer.nading@trinity-health.org](mailto:jennifer.nading@trinity-health.org).

Sincerely,

/s/

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Trinity Health