



March 7, 2022

Chiquita Brooks La-Sure
Administrator
Centers for Medicare and Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-4192-P; Medicare Program: Contract Year 2023 Policy and Technical Changes to the Medicare Advantage and Medicare Prescription drug Benefit Programs

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

Dear Administrator Books La-Sure

Trinity Health appreciates the opportunity to comment on policies set forth in CMS-4192-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 115,000 colleagues and nearly 26,000 physicians and clinicians caring for diverse communities across 25 states. Nationally recognized for care and experience, the Trinity Health system includes 88 hospitals, 131 continuing care locations, the second largest PACE program in the country, 125 urgent care locations and many other health and well-being services. Based in Livonia, Michigan, its annual operating revenue is \$20.2 billion with \$1.2 billion returned to its communities in the form of charity care and other community benefit programs.

Trinity Health has 17 Clinically Integrated Networks (CINs) that are accountable for approximately 1.5 million lives across the country through alternative payment models. Our health care system participates in 14 markets with Medicare Shared Savings Program (MSSP) Accountable Care Organizations (ACOs), which includes eleven markets partnering in one national MSSP Enhanced Track ACO, Trinity Health Integrated Care. Two of the 14 markets also participate in CPC+. In addition, we have 33 hospitals participating in the Bundled Payments for Care Improvement Advanced (BPCIA) initiative, and three hospitals in the Comprehensive Care for Joint Replacement (CJR) program. Our work—and experience in value-based contracting—also extends beyond Medicare as illustrated by our participation in 123 non-CMS APM contracts.

Throughout the COVID-19 pandemic, Trinity Health has focused on supporting the most vulnerable in our communities. We have collaborated with local public health and community partners to provide medical services to those who are experiencing homelessness, uninsured, underinsured or with Medicaid, and/or lack the resources to obtain care.

In collaboration with community health workers, Trinity Health expanded our social care hubs. These hubs have been able to connect community members to food, housing, financial assistance, and primary medical

care. CHWB has made over 314K social care encounters (engagement between health system and patient/community member to address social needs) in FY22.

In 2020, our Transforming Communities Initiative provided more than \$500,000 in funding to underserved communities to support COVID-19 needs. Committed to equitable access, we have supported mobile testing and pop-up vaccine clinics at churches and community centers, focusing on communities who that have limited time and resources to access health care. In addition, Trinity Health invested \$2.6 million in our “It Starts Here” vaccine outreach and education campaign to amplify the message that vaccines save lives and provide easy access within the community to receive the vaccine.

Prior Authorization

Trinity Health believes prior authorization plays an important role in our nation's health system by making sure expensive resources, such as inpatient rehabilitation and long-term acute care, are utilized judiciously. However, we have experienced many Medicare Advantage (MA) plans use prior authorization requirements in ways that create dangerous delays in care, contribute to clinician burnout, and drive up health system costs.

Specifically related to the RFI, prior authorization requirements for patient discharges to post-acute care (PAC) settings have created significant challenges, especially during the COVID-19 pandemic. **We encourage CMS, working with Congress as necessary, to require plans to waive these administrative processes during public health emergencies (PHEs) and identify a long-term policy solution beyond the PHE.** Continued flexibility and adoption of prior authorization waivers by MA plans would materially improve pandemic responses across the country.

In order to best care for our community during the COVID-19 pandemic, we needed to quickly turn over general acute-care hospital beds and create space for higher-need COVID-19 patients, as well as ensure access to the appropriate level of care for those recovering from the virus. This necessitated urgent modifications to traditional discharge processes and clinical pathways to optimize personnel, physical plant and other resources. The flexibilities offered by CMS to relax or waive prior authorization requirements for MA plans were invaluable for general acute-care hospitals in implementing these modifications.

However, a substantial limitation of this flexibility is that it encouraged, but did not mandate, that MA plans waive such processes. While many MA plans worked collaboratively with provider partners to waive or relax onerous prior authorization requirements during the PHE, others did not, or only did so during the initial stages. The continued use of prior authorization and other health plan utilization management policies by some plans throughout the pandemic has prevented referring hospitals from utilizing desperately needed health system capacity in PAC settings. This has been especially problematic when general acute-care beds have been filled to capacity and while hospitals contend with the demands of vaccine distribution and workforce shortages. have unintended consequences for patients who are then forced to stay in acute care settings unnecessarily while waiting for health plan administrative processes to authorize the next steps of their care. Even today, these challenges persist.

While 21 national and regional/state payers that contract with Trinity Health facilities waived prior authorization requirements for post-acute care, 17 payers did not. Of the payers that did waive the requirements, most began implementing targeted prior auth waivers in 2021—typically only issuing prior authorization waivers for those locations experiencing a surge and usually time-limited (e.g. 30 days). While we saw many payers issue waivers at the beginning of the PHE, less did so as time went on and those that maintained their waivers did so in the targeted manner.

Unwarranted Prior Authorization Delays Harm Patient Care

It is clear that keeping patients in the emergency department or an inpatient bed while waiting for the health plan's decision or response to a prior authorization request is not in the best interest of the patient. These delays often result in missed clinical opportunities for patients to access the more-specialized care typically provided in PAC settings. This is a clear detriment for patients with or recovering from COVID-19 whose condition requires interdisciplinary and targeted PAC care that combines medical care and rehabilitation. This is particularly important for high-complexity patients and those experiencing cases of "long-COVID-19." Such delays due to prior authorization requirements also can interfere with patients' prescribed PAC plan of care, which is established by the referring hospital's treating physician and clinical team, and is intended to help patients return to their home or community sooner. When patients are delayed from being transferred to more appropriate clinical settings that focus on both medical and rehabilitative needs, their PAC plan of care cannot be implemented as intended, and progress toward their recovery is often negatively affected.

These concerns are consistent with the findings of a September 2018 report by the Department of Health and Human Services Office of Inspector General (OIG), which warned that high rates of MA health plan payment denials and prior authorization delays could negatively impact patient access to care.¹ Further, a 2021 survey by the American Medical Association of more than 1,000 physicians underscores the negative impact on patient care resulting from prior authorization. The survey 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 10 physicians (93%) 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.²

General Acute-Care Hospitals' PHE Capacity Needs to Be Augmented by PAC

During the pandemic, some general acute-care hospital patients could wholly or in part receive clinically-appropriate care in another setting, such as a long-term care hospital, inpatient rehabilitation facility or skilled nursing facility. However, prior authorization requirements frequently delayed or prevented discharge in these cases, requiring general acute care hospitals to allocate clinical resources to manage patients who could otherwise be safely discharged. Utilization of PAC settings is a critical component of the health system's necessary response to a PHE, and health plan administrative processes should not supersede the imperative to free up general acute-care hospital capacity and facilitate patient transfers to other settings where clinically appropriate.

Further, from a PAC perspective, there are widely-held concerns about the behavior of MA plans who approve prior authorization requests for PAC, but later issue retrospective denials for the same services. This has been a long-standing and problematic issue for many PAC providers and the resulting hesitancy also contributed to delays in patient transfers from general acute-care hospitals to PAC facilities during the PHE.

Health Plans' Adding Administrative Burden to the National PHE Response. Many MA plans use inconsistent administrative protocols and a dizzying array of timelines and requirements for prior authorization

¹ U.S. Department of Health and Human Services, Office of Inspector General (OIG). "Medicare Advantage Appeal Outcomes and Audit Findings Raise Concerns about Service and Payment Denials." September 25, 2018. <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.

² American Medical Association, "2021 AMA Prior Authorization (PA) Physician Survey." Accessed at: <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>.

requests, reviews, approvals and communication, which are unnecessary at best, but rise to the level of unconscionable during a PHE. Excessive requirements and variation between them adds burden to the system as providers and their staff must ensure they are following the right set of rules and processes for each plan, which may change from one request to the next, and can also vary by plan, product and vendor. Despite the tremendous time and resources needed to comply with such extensive requirements, prior authorization requests are often returned multiple times to provide additional information and are further delayed by slow health plan responses, which typically do not occur outside traditional business hours. During a time of national emergency where workforce shortages and strained health system capacity have been persistent challenges, there is simply insufficient bandwidth to comply with such cumbersome administrative procedures.

Prior authorization processes also have exacerbated workforce challenges and contributed to physician and other staff burnout during the PHE. Hospitals often have multiple full-time employees whose sole role is to manage health plan prior authorization requests. These staff often are physicians and nurses who have been diverted from patient care. Part of the challenge stems from health plans' use of peer-to-peer calls to establish prior authorization for a service or treatment without providing access to clinicians with the right type of expertise. Physicians report that their offices spend on average two business days of the week dealing with prior authorization requests, with 88% rating the burden level as high or extremely high.³

Lack of Transparency of Clinical Guidelines

Health plans commonly use medical necessity criteria and other clinical guidelines for general acute-care hospital and PAC admissions, which differ by plan and deviate from those used by fee-for-service (FFS) Medicare. These modifications often are deemed proprietary and not shared with providers, resulting in a black box methodology for determining whether a service is medically necessary. As a result, it becomes nearly impossible for providers to anticipate what the health plan might request as evidence of medical necessity pursuant to a criteria that they will not share.

As a result of this lack of transparency in clinical guidelines, there is often extensive back and forth between providers and health plans in response to insurer requests for excessive amounts of documentation to substantiate the need for particular services. It is not uncommon for health plans to request information that is not directly relevant to making a determination about whether post-acute care is needed (e.g., when evaluating a prior authorization request for rehabilitation services, requesting information on a medication that would not impact the need for rehabilitation services). Further, with regard to transitions to PAC, many plans apply their medical necessity criteria based on the subjective judgment of clinicians with limited or no knowledge of PAC.

Overuse of Prior Authorization

Some health plans require prior authorization even for services where there is no evidence of abuse and for which the standards of care are well established.

Specifically for PAC services, health plans frequently deny the presence of medical necessity for services that are supported by the literature and that are covered by FFS Medicare. For example, despite clear clinical guidelines directing providers to place certain medically-complex stroke patients in inpatient rehabilitation

³ <https://www.ama-assn.org/system/files/prior-authorization-survey.pdf>.

facilities for a combination of medical and intensive rehabilitation services, health plans commonly require prior authorization or even deny this service.

OIG Found Unwarranted MA Denials

The majority of the prior authorization and coverage denials are for covered, medically necessary services that are rejected for administrative processing reasons as opposed to concerns about the legitimacy or appropriateness of the service. Generally in these cases, clinicians treat patients using their best medical judgment, but too often their expert opinion is overridden by the plan (and often by a clinician without relevant expertise in the particular specialty or PAC discipline). Ultimately, many of these denials are overturned through time-consuming administrative appeals. The September 2018 OIG report referenced earlier found that among appealed cases, MA plans overturned 75% of their own denials between 2014-2016 (approximately 216,000 denials per year) through their own appeals processes.⁴ These findings highlight a pattern of health plans inappropriately denying access to services and payment that should have been provided.

Conclusion

Thank you for your attention to these issues. We know MA plans can do better because Trinity Health has an MA plan, MediGold, which plays a vital role in our integrated delivery network and provides key care coordination for our patients. MediGold utilizes Milliman Care Guidelines for many decisions on precertification and other authorization approval processes, removing ambiguity of guidelines for providers. The way MediGold operates demonstrates that the aggressive tactics deployed by some MA plans is not necessary for success. If you have any questions, please feel free to contact me at jennifer.nading@trinity-health.org or 202-909-0390

Sincerely,

/s/

Jennifer Nading
Director, Medicare and Medicaid Policy and Regulatory Affairs
Trinity Health

⁴ <https://oig.hhs.gov/oei/reports/oei-09-16-00410.asp>.