DRAFT March 13, 2023

Administrator Chiquita Brooks-LaSure
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: CMS-0057-P: Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule

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Dear Administrator Brooks-LaSure:

The Health Care Transformation Task Force (Task Force) appreciates the opportunity to respond to the Advancing Interoperability and Improving Prior Authorization Processes Proposed Rule (Proposed Rule).

The Task Force is a multi-stakeholder consortium that supports accelerating the pace of transformation in the delivery system through the adoption of value-based care delivery supported by aligned payment models. Representing a diverse set of organizations from various segments of the industry – including providers, payers, purchasers, and patient advocacy organizations – we share a common commitment to transform our respective businesses and clinical models to deliver a health system that achieves equitable outcomes through high-quality, affordable, person-centered care. We strive to provide a critical mass of policy, operational, and technical support that, when combined with similar efforts by CMS and other public and private stakeholders, can increase the momentum of meaningful delivery system transformation.

I. General Comments

Prior authorization is a well-documented point of friction between payers, providers, and patients. In a fee-for-service payment environment that incentivizes volume over the value of services, payers have a legitimate need for tools to discourage inappropriate service utilization and encourage the use of evidence based and cost-effective care. However, the complexity and variability of prior authorization requirements across payers, individual insurance products, providers, and patients can create significant administrative burdens for all stakeholders involved. Patients face the stress of navigating an often-confusing prior authorization system to get approvals for care. The amount of time payers spend on prior authorization determinations can delay care. Additionally, providers may add to that delay by submitting incomplete data or unnecessarily seeking prior authorization as protection against possible coverage denials. In short, the current prior authorization process is burdensome and ineffective for all stakeholders and presents a clear opportunity for improvement. The Task Force believes that payment reform, specifically the broad adoption of value-based payment models focused on the value of care provided rather than the volume of services, has the potential to greatly reduce or eliminate the need for prior authorization. Because true value-based transformation is a long-term endeavor, we also support more immediate efforts by CMS to incrementally improve prior authorization policies.

The Task Force views effective data sharing and system interoperability as critical to advancing the health system transformation at the core of the Task Force's mission. We applaud the focus CMS has placed on advancing these issues through the use of standard application programming interfaces (APIs). Health care data are generated at every stage of patient care, from the time they enter the health care system to the time they leave. Sharing these data across the healthcare continuum, from payers to providers and patients, will facilitate a more comprehensive understanding of patient health and improve the quality of outcomes through the benefits of coordinated care.

Standardization around interoperability requirements and APIs promote the streamlined exchange of data between disparate actors and systems. This can reduce the administrative burden on healthcare providers and plans, minimize errors, and increase the efficiency of care delivery. As efforts continue to address issues with prior authorization, CMS should incentivize payers and providers to invest in technology that allows for rapid prior authorization determinations to significantly reduce administrative burdens and minimize delays in care. Additionally, expanding access to data improves transparency for patients, allowing them greater control over their health information and a better understanding of their covered benefits. Finally, increasing access to more comprehensive and accurate data benefits payers by reducing duplicative services, improving the accuracy of prior authorization determinations, and reducing a primary point of friction between plans, providers, and patients.

HCTTF supports the Proposed Rule's policy goals. However, we note that some Task Force members have raised concerns with the lack of a) well-defined data standards and transaction sets for prior authorization information, b) maturity of existing implementation guides, and c) specificity and flexibility in CMS' proposed approach to defining technical standards. These issues are critical to support the successful interoperable exchange of prior authorization related data. The Task Force recommends CMS prioritize the development of the content and technical standards for testing and ongoing stakeholder engagement regarding these policies to minimize the potential for unnecessary variation and ensure successful implementation. The Task Force offers more detailed feedback on the specific provisions of the proposed rule in the sections below.

II. Patient Access API

A stated CMS goal in the Proposed Rule is to improve transparency to patients around decisions made about their care. CMS proposes requiring impacted payers – Medicare Advantage (MA) organizations, state Medicaid and Children's Health Insurance Program (CHIP) Fee-for-Service (FFS) programs, Medicaid managed care and CHIP managed care entities, and Qualified Health Plan (QHP) issuers on the Federally Facilitated Exchange (FFE) – to develop and maintain a Patient Access API, which would give patients access to claims, encounter, and clinical data no later than one business day after a claim is adjudicated or encounter or clinical data are received. Additionally, CMS proposes requiring payers make information about prior authorizations available through the Patient Access API no later than one business day after the payer receives the prior authorization request or there is another type of status change for the prior authorization. Information to be included relating to the prior authorization request are the status, date the prior authorization was approved or denied, date or circumstance under which the authorization ends, items and services approved, quantity used to date under the authorization, and reason for denying a prior authorization request. CMS proposes a compliance date of January 1, 2026 for making data available via the API.

In addition to a Patient Access API, CMS proposes to require payers to report annual metrics to CMS on patient use of the API, including the number of unique patients whose data are transferred via the Patient Access API to a health app, and the total number of unique patients whose data are transferred more than once.

The Task Force generally supports CMS' proposal for updates to the currently mandated patient access API to expand patient access to and transparency around decisions impacting their care. We agree with CMS that the API would improve transparency to patients about prior authorization decisions impacting their care. Access to this information allows patients to have greater understanding of the decisions being made about their care and greater control of their health information to aid in shared decision making with their provider. Information provided through an API would also be timelier than sharing through postal mail and would more effectively reach patients who are moving, residentially unstable, or unhoused. The Task Force also supports annual reporting of baseline metrics for patient use of the API so CMS can measure the uptake of this information among patients to determine the level of interest among beneficiaries, as well as to identify barriers such as a lack of technology that may be limited beneficiary engagement. The Task Force recommends that 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.

III. Provider Access API

CMS proposes that payers implement and maintain a Fast Healthcare Interoperability Resources (FHIR) API that makes patient data available to providers with a treatment relationship with an enrollee and in a contractual agreement with the payer by January 1, 2026. This Provider Access API would allow providers to initiate requests when they need access to patient data prior to or during a patient visit. Rather than accessing this information to send to a health app, as is the case with the Patient Access API, data would flow from the payer to the provider's electronic health record (EHR) or other practice management tool. Available information would include immunizations, procedures, assessment and plan of treatment, and prior authorization requests and decisions. Impacted payers would be required to make patient data available to a provider within one day of the request. CMS proposes a compliance date of January 1, 2026 for making data available via the API. The Proposed Rule would require that payers address the following areas:

- **Attribution:** Develop an attribution process to associate enrollees with their providers to help ensure that a payer only sends an enrollee's data to providers who request that data and have a treatment relationship with that patient.

- **Opt-Out:** Establish and maintain an option for a patient to opt-out of having their data made available for providers through the Provider Access API. In addition to a patient opt-out option, CMS is encouraging payers to implement processes for patients to select individual providers with whom the payer should not share data. CMS states that they believe this latter option would drive a more patient-centered process by eliminating that all or nothing outcome when enrollees choose to be more selective.
- **Patient Resources Regarding the Provider Access API:** Provide information to plan enrollees about the benefits of the Provider Access API requirements, their opt-out rights, and instructions both for opting-out of the data exchange and for opting-in after previously opting-out. Payers would be required to provide this information in non-technical, simple, and easy to understand language, at the time of enrollment and annually thereafter.
- **Provider Resources Regarding the Provider Access API:** Develop non-technical and easy-to understand educational resources for providers about the Provider Access API, including the process for requesting patient data from the payer using the API and how to use the payer's attribution process to associate patients with the provider.

The Task Force generally supports CMS' proposal for a Provider Access API that makes patient data available to providers in accordance with the wishes of enrollees. Similarly to the Patient Access API, the Task Force believes that the Provider Access API will offer timely data to providers to support decision making between enrollees and the provider about the patient's health. Access to this information allows providers with a treatment relationship with an enrollee to improve care by addressing treatment needs in a more timely manner.

HCTTF members raised several issues for CMS consideration. Specifically, some HCTTF members have noted that:

- API standards should ensure that prior authorization information clearly indicate to payers and providers whether a request is flagged as urgent or standard.
- Binary opt-in and opt-out policies may result in patients restricting sharing of all data out of concern over sharing data for only specific conditions or treatments. CMS may consider leveraging existing privacy laws – which already allow patients to restrict use of their information – to allow patients to elect to share r withhold more granular categories of data.
- CMS and ONC should explore ways to promote provider uptake of the provider Access API.

IV. Payer-to-Payer Data Exchange

CMS proposes requiring payers to exchange enrollees' health information, at the enrollees' request, with other payers when an enrollee changes health plans. This information would include claims and encounter data (excluding cost information), data elements identified in the United States Core Data for Interoperability version 1, and prior authorization requests and decisions. This requirement's goal is to create a longitudinal health record, maintained with an enrollee's current payer, that follows them throughout their health care journey. If an enrollee has concurrent coverage with two or more payers, the Proposed Rule would require the impacted payers to make the enrollee's data available to the concurrent payer at least quarterly. CMS proposes a compliance date of January 1, 2026 for this provision.

The Task Force generally supports CMS' proposal for a Payer-to-Payer data exchange for enrollees that are covered by multiple payers or transitioning between payers. We agree with the CMS assessment that such data sharing would improve the completeness and quality of patient data through a longitudinal record and support better care coordination for patients. Furthermore, HCTTF is actively working on advancing multi-payer alignment strategies and believes that investments made in establishing standardized transactions for payer-to-payer data sharing would benefit broader multi-payer alignment efforts. Nonetheless, we note that one Task Force member raised concerns that CMS' proposal will create significant operational challenges for payers and may require the sharing of large amounts of unnecessary data.

In the preamble of the NPRM, CMS seeks comment on how these proposals could apply to Original Medicare. The Task Force supports improving data interoperability across all payers, including Original Medicare. Notably, a HCTTF member has proposed CMS develop an API mirroring the current AB2C API – used for data sharing between Part C stand-alone drug plans and Original Medicare – that would enable Original Medicare to share data with MA plans. We encourage CMS to explore the future development of API requirements that facilitate bi-directional data exchange between Original Medicare and MA plans so that Medicare data effectively follows the patient across the program.

V. Improving Prior Authorization Processes

CMS proposes requiring impacted payers to build and maintain a FHIR API for Prior Authorization Requirements, Documentation and Decisions (PARDD API). This PARDD API would automate the process for providers to determine whether a prior authorization is required, identify prior authorization information and documentation requirements, and facilitate the exchange of prior authorization requests and decisions from provider EHRs or practice management systems. CMS proposes a compliance date of January 1, 2026 for this provision. The Proposed Rule would require that payers:

- **Denial Reason**: Include the reason for a prior authorization denial regardless of the method used to send the prior authorization decision. This is intended to improve communications between providers and payers and facilitate more accurate resubmission of the prior authorization requests and appeals if necessary.
- **Time Frames:** Send prior authorization decisions within 72 hours for expedited/urgent requests and seven calendar days for standard/non-urgent requests. CMS is also seeking comment on requiring shorter turnaround times, for example, 48 hours for expedited requests and five calendar days for standard requests.
- **Prior Authorization Metrics:** Publicly report prior authorization metrics annually on their websites. Reporting would occur at the organization level for Medicare Advantage plans, the plan level for Medicaid and CHIP managed care, and at the state level for fee-for-service Medicaid and CHIP programs. Reporting

requirements would include a list of all items and services requiring prior authorization, the median time between a request and decision determination, as well as the percentage of prior authorization requests that were approved, denied, approved after appeal, and had a timeframe extension before approval – stratified by standard vs. expedited requests.

HCTTF generally supports the goals of the proposed PARDD API requirements. As stated earlier, the Task Force believes that effective delivery system reform, specifically the broad adoption of value-based care delivery protocols and aligned payment models, has the potential to greatly reduce or eliminate the need for prior authorization. Short of such a fundamental shift in our care system, requirements meant to help providers and payers automate the prior authorization functions, reduce administrative burden, and improve transparency around the prior authorization process are a significant positive step in the right direction.

That said, HCTTF members have noted potential issues and opportunities with the PARDD requirements regarding PA time frames and metrics. We urge CMS to take these into consideration when finalizing the rule. Specifically, CMS should consider:

- **Providing additional clarity on time frames** for prior authorization approvals. Several HCTTF members raised concerns that a lack of clarity in turnaround time requirements could result in unnecessary denials due to delays in responding to requests for additional information received outside of normal business hours. To this end CMS should clarify when the clock starts for the review of PA requests and consider an option for responding with "pending additional information" in addition to an approval or denial.
- **Incentivizing providers to adopt electronic Prior Authorization (ePA)** and connect to APIs to successfully advance interoperability and reduce the administrative burden of PA. This could include expanding the proposed MIPS measure of provider uptake of ePA to also apply to non-MIPS providers and developing and piloting incentive programs to support providers (especially those not included in the Meaningful Use Program, such as behavioral health providers) to invest in the necessary health IT systems as recommended in the SUPPORT Act.
- **Engaging with impacted payers to address concerns that publicly reported PA metrics** may not be comparable across organizations and plans due to variations in underlying provider and patient populations. This issue could result in users of this data focusing solely on overall PA rates rather than important factors such as the reason for a denial or the appropriateness of a payer's use of PA for addressing concerns about quality, efficacy, and low-value care.
- **Addressing other areas of care were PA policies impact clinical care and treatment decisions.** Specifically, HCTTF members noted that this Proposed Rule does not address the PA processes for prescription drugs. Given the complexity of PA for prescription drugs, we encourage CMS to explore PA policies to address this issue in future rulemaking and consider the development of pilot programs to identify the best strategies for managing the high volume of prescription drug prior authorization requests.

VI. Requests for Information:

RFI: Accelerating the Adoption of Standards Related to Social Risk Factor Data

Addressing health inequities begins with collecting person-level data on individuals' race, ethnicity, language, sexual orientation and gender identity, disability status, socio-economic status, and geographic location. Person-level demographic data are critical for the purpose of stratifying clinical process and outcome measures to gain a granular understanding of the inequities in care, and disparities in outcomes, that fall along demographic and other characteristics' lines. Without these data points, it is extremely difficult payers and providers to understand the factors that are driving enrollees' health status and outcomes, and the gaps in care that they are experiencing. Comprehensive person-level data is critical to the process of identifying benefits needs, as well as care delivery modalities that will best suit enrollees and implement strategies and interventions to maximize effective patient care.

The Task Force fully supports efforts to improve and increase the collection of SDOH data. We believe that these options can and should be designed in a way that would make it feasible for payers and providers to consistently collect data in a standardized manner without creating undue burden when better data sources may already be available. In addition, we recommend CMS create educational resources for Medicare beneficiaries that assist payers and providers and educate patients as to why these data are being requested, and for what purposes they will be used. While stakeholders understand that these data are critical to the ability to develop meaningful interventions and policies that help patients, several Task Force members note that personal information is being asked of patients, without the requisite time spent providing patients with a clear rationale. When a provider codes a patient's SDOH codes via an EHR or other form of collection, that screening and result will show up on the patient's after-visit summary, which many patients may find concerning. The process of improving patient-reported data requires a foundation of trust; we encourage CMS to consider its role in addressing this need.

Currently the field is facing the dual challenge of collecting SDOH data, and subsequently being able to access these data in a standardized format. Providers and payers are striving to address these challenges, in clear recognition of the need for standardized social determinants of health (SDOH) data. Health plans, hospitals, and clinicians are currently following various federal and state requirements for demographic and social needs data collection related to Medicare, Medicaid, Qualified Health Plans, and others, and additional proposals are being floated. **The Task Force believes that any approach that is applied to MA should be aligned and standardized – to the extent feasible – across federal programs**

One strategy that CMS described during the 2022 rulemaking cycle was using existing z-codes as a tool for standardized data collection. However, available ICD-10 z-codes that are relevant to SDOH coding do not always align with EHR-based SDOH screening tools. There is also apparently a lack of alignment between z-codes and ONC/HIT certification requirements. Given that the submission of z-codes to document patient characteristics does not affect reimbursement, the use of these codes by providers in the inpatient setting has been inconsistent at best. One Task Force member notes that for optimal uptake, SDOH should be aligned with health and social needs gaps identified in local communities; however, the current range of z-codes do not allow for this localized approach. Finally, some members note that it is unclear how to apply z-codes to SDOH screening.

The ability to recognize severity of illness and utilization of resources is critical to addressing health inequities and establishing interventions to best support patients' needs. Thus, we recommend CMS consider developing a broader strategy for collecting SDOH data that leverages technology available across multiple settings and does not impose an additional data collection burden on providers. One option is to work with EHR vendors to consider opportunities for advanced adoption of USCDI Version 3, which includes categories of data elements that capture health status (including health concerns, functional status, disability status, and mental function), demographics (including race, ethnicity, tribal affiliation, sexual orientation, gender identity and preferred language), and problems (including SDOH concerns) so these data can be appropriately requested via the APIs from EHRs. We also support efforts to align Medicare enrollment forms with the USCDI Version 3 data standards, and suggest CMS support ongoing SDOH standards development, --such as the HL7 Gravity Project -- and leverage existing data collection efforts by coordinating the use of already-collected SDOH data via EHRs.

Finally, **the Task Force offers two suggestions: 1) we encourage CMS to solicit and review existing best practices being implemented in the field to increase the volume and accuracy of person-level self-reported data.** These practices include not only the data collection process itself, but the foundational efforts to build trust between providers/payers and patients that enables information collection and provide support to payers and providers to enable their ability to successfully capture these data. **2) we urge that any SDOH screening instruments go through rigorous cross-cultural validation**. Without such validation, there is the potential to under- or over-report unmet need in certain communities, and inadvertently develop or exacerbate existing disparities within communities.

RFI: Electronic Exchange of Behavioral Health Information

The Health Information Technology for Economic and Clinical Health Act (HITECH) passed in 2009 promotes and expands the adoption of health information technology, with a specific focus on the use of electronic health records by healthcare providers. However, as discussed in a recent MACPAC meeting, the HITECH program struggles to make an impact in the behavioral health space. The incentive program offered in HITECH does not completely offset the costs for behavioral health providers. Behavioral health providers are already often less likely to invest in the hardware, software, and training necessary for EHR adoption because of narrower operating margins. Lower participation in EHRs leads to lower participation in Health Information Exchanges (HIE). Further, the incentives in the program do not extend to other behavioral health workers – such as psychologists and social workers in psychiatric hospitals - working within behavioral systems. The Task Force recommends CMS focus on addressing these issues, potentially by developing incentivizes for behavioral health providers to implement EHRs and participate in data exchange for the purpose of more effective care coordination for patients with behavioral and physical health needs.

In a 2017 comment letter, the Task Force encouraged CMMI to coordinate with SAMHSA to increase flexibility and modernize patient data sharing requirements; the Task Force continues to echo these comments here to amplify their importance. The Task Force also supports the inclusion of consent policy best practices in future behavioral health models, including an examination of the limitations presented by the 42 CFR Part 2 provisions on the ability for providers to engage in the recommended data sharing approaches and provide high quality treatment and care coordination that addresses all patient health needs. Suggestions from the September 2021 MACPAC meeting include creating a consent mechanism program that can be incorporated into existing EHRs.

The Task Force appreciates the opportunity to respond to this proposed rule. Please contact HCTTF Senior Director Joshua Traylor (Joshua.traylor@hcttf.org) with any questions.

Sincerely,

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