

RE: Request for Information on Regulatory Relief

Recommendations for Regulatory Reform

Streamline Regulatory Requirements

- Are there existing regulatory requirements (including those issued through regulations but also rules, memoranda, administrative orders, guidance documents, or policy statements), that could be waived, modified, or streamlined to reduce administrative burdens without compromising patient safety or the integrity of the Medicare program?

Streamline and Refocus Hospital Price Transparency Requirements (Relevant Regulations: 45 CFR § 180; 42 CFR § 447.254; CMS-1717-F2 (CY 2020 Outpatient Prospective Payment System Final Rule))

We recommend streamlining and aligning federal price transparency rules across agencies and with states to emphasize actionable, understandable information for families—such as expected out-of-pocket costs—rather than technical file formats. A consolidated framework, appropriately adapted for pediatric hospitals, would reduce burden and enhance the impact and consumer usability of the price and cost information that is shared.

Children's hospitals support the goal of making health care costs more transparent for families. However, current federal price transparency requirements—when combined with overlapping state mandates and No Surprises Act implementation—create a fragmented and duplicative reporting burden. These requirements offer limited value to families while demanding significant administrative resources that divert attention away from medically necessary care and treatment.

The CMS May 22, 2025 Updated [Hospital Price Transparency Guidance](#) and [FAQs](#) adds to that fragmentation by requiring hospitals to encode dollar amounts in machine readable files where calculable. While this new requirement may improve consistency for researchers and aggregators, it exacerbates the existing lack of consistency across the various federal and state price transparency requirements, adds to the administrative burden for hospitals and, most importantly, does not meaningfully help families understand what they actually owe – the purported goal of these policies. Instead, the inconsistencies in requirements means that families may receive different pricing information from hospitals and from payers, which complicates their care navigation, contributes to care delays, and can negatively impact health outcomes for pediatric patients—while also driving up unnecessary administrative costs for hospitals.

Furthermore, in pediatrics, it is not uncommon for a child, particularly a child with a chronic or complex medical condition to have coverage through multiple payers (i.e., commercial insurance with Medicaid coverage for the services that private plans do not cover). Providing clear, accurate out-of-pocket cost estimates in these cases is significantly more complex and can delay or deter timely care as providers try to help families understand the information and the nuances of their commercial versus Medicaid coverage and out-of-pocket obligations.

At the same time, the burden of maintaining separate systems to comply with overlapping federal and state rules is significant and costly. Children's hospitals must build and maintain different systems to meet each set of requirements, including the most recent guidance, even when those systems do not support meaningful comparisons or improve decision-making for families.

Withdraw the Information Blocking Provider Disincentives Rule (Relevant Regulations: 21st Century Cures Act: Establishment of Disincentives for Health Care Providers That Have Committed Information Blocking (89 FR 42980; RIN 0955-AA05); 42 CFR § 495.24 and § 495.40 (Promoting Interoperability Program), 42 CFR § 414.1380 (MIPS Promoting Interoperability), 42 CFR § 425.500 et seq. (Shared Savings Program))

CMS and the ASTP/ONC should withdraw these recently enacted information blocking penalties and disincentives as they do not adequately reflect the unique clinical, technical, and legal contexts of children's health care. These penalty structures impede, rather than enhance, the exchange of health care information and improved child patient outcomes. In particular, the final rule fails to

Children's hospitals and pediatric providers face a unique set of challenges when navigating federal information blocking rules. First, they must manage a complex web of state and federal privacy laws—many of which vary by state and patient age—while also attempting to comply with federal data sharing mandates. Current technology and policies do not offer a reliable way to fully align these requirements, creating unavoidable compliance barriers for children's hospitals. For example, they must comply with adolescent confidentiality laws that vary significantly by state. At the same time, pediatric providers must often restrict or carefully manage access to information for their young patients in order to prevent emotional harm or confusion. For instance, automatic release of sensitive diagnoses to an adolescent patient without the opportunity for a provider to offer clinical context could inadvertently cause distress or misinterpretation.

In addition to adolescent confidentiality, neonatal care poses significant privacy risks tied to maternal health information. Newborn medical records often include maternal health history — such as details on substance use, sexually transmitted infections, or genetic conditions — that may be protected under HIPAA or other state laws. Providers must be able to tailor access to these records to protect maternal privacy and ensure family safety. The current disincentives framework does not account for these scenarios and may discourage proper documentation or communication between care teams. Penalizing providers for these practices— particularly under broad or ambiguous information blocking standards — undermines their ability to exercise sound clinical judgment while complying with HIPAA and local law.

From a technical perspective, children's hospitals frequently work with large networks of community-based pediatricians, schools, and specialty providers, many of which do not use certified electronic health record technology or are on incompatible platforms. In such cases, children's hospitals cannot control how data is shared, yet they may be held responsible for perceived information blocking due to interoperability limitations beyond their control.

Compounding these challenges, the rule's penalty mechanisms are implemented through CMS programs that largely exclude pediatric providers, such as the Medicare Promoting Interoperability Program, the Merit-Based

Incentive Payment System, and the Shared Savings Program. Many children's hospitals are exempt from these programs due to low Medicare patient volume, making the use of these levers both confusing and ineffective. Furthermore, the Office of Inspector General's enforcement approach remains underdeveloped, with limited clarity on what constitutes a violation or how providers can appeal a finding, raising due process concerns.

- Which specific Medicare administrative processes or quality and data reporting requirements create the most significant burdens for providers?

Conditions of Participation (CoPs) (42 CFR § 482)

Children's hospitals support the Medicare Conditions of Participation (CoPs) as a critical mechanism for ensuring safe, high-quality care. However, these requirements are often based on adult hospital models and fail to account for the clinical, operational, and developmental needs of pediatric care. Additionally, many clinical policies within CoPs are highly detailed in ways that limit the ability of providers to tailor care practices to their child patient population. This disconnect can result in regulatory requirements that are not meaningful or appropriate for children's hospitals. Children's hospitals have identified the following CoP-related regulations as particularly burdensome, and we offer recommendations to reduce unnecessary complexity while maintaining patient safety and quality of care.

- **Revise Home Health Authorization and CoPs for Chronically Complex Pediatric Patients** (Relevant Regulations: 42 CFR § 484.50–484.75)

CMS should work with pediatric providers to revise home health CoPs to reduce documentation frequency for stable pediatric patients, eliminate adult-specific assessment criteria for pediatric cases, and consider pediatric-specific guidance or flexibilities. Such changes would reduce unnecessary administrative costs, improve continuity of care, and better align federal home health oversight with modern pediatric care delivery.

Children's hospitals are increasingly supporting care for children with medically complex conditions in the home, often through partnerships with home health agencies (HHAs). However, current CoPs for HHAs create significant administrative burdens when applied to pediatric populations with long-term, stable needs.

The current CoPs were designed decades ago for adult patients recovering from acute events and do not reflect the evolving reality of pediatric chronic care home care, where children with complex, often lifelong conditions require ongoing services such as private duty nursing. For example, current requirements to reassess care plans every 60 or 90 days create unnecessary and duplicative documentation cycles for children whose medical needs are unlikely to change in that timeframe. This administrative burden diverts resources from direct patient care, delays authorizations and impedes timely service delivery. Additionally, CoPs include adult-focused criteria — such as assessments for grocery shopping or other independent living skills — that are irrelevant to pediatric patients but still must be documented by pediatric providers for compliance.

Opportunities to Reduce Administrative Burden of Reporting and Documentation

• What changes can be made to simplify Medicare reporting and documentation requirements without affecting program integrity?

Modernize and Consolidate Physical Notice Requirements (Relevant Regulations: 42 CFR § 482.13, 45 CFR § 164.520, and related CMS Conditions of Participation)

CMS should streamline and modernize physical notice requirements by consolidating duplicative postings, allowing digital alternatives where appropriate, and prioritizing clarity and accessibility for patients and families.

We strongly support clear, accessible public notice requirements that inform patients and families of their rights and protections. Transparent communication is essential to supporting patient-centered care, especially in pediatric settings where caregivers must navigate complex medical systems on behalf of their children. We encourage CMS to modernize these requirements to ensure that the required information is delivered in a format that is meaningful and usable for families.

Currently, children's hospitals are subject to overlapping federal and state mandates to post or distribute notices on patient rights, privacy practices, and other policies and practices. These requirements often include highly specific directives on formatting, font size, and placement in "prominent locations." As a result, hospitals are producing and posting increasingly lengthy documents that dilute the visibility of time-sensitive or critical information. Additionally, constant regulatory updates generate ongoing costs for reprinting and redistributing materials. Reducing redundancy and enabling modern communication formats would help ensure that key information remains accessible and reduces unnecessary administrative burden.

Standardize and Streamline Electronic Prior Authorization for Pediatric Providers (Relevant Regulations: CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F); 42 CFR Parts 414, 423, 431, 457, and 438)

We urge CMS to prioritize the full implementation and enforcement of the CMS Interoperability and Prior Authorization Final Rule (CMS-0057-F) and extend its standards across Medicaid and the Marketplaces.

The burden of navigating manual and inconsistent prior authorization systems continues to fall heavily on pediatric providers. Standardizing and enforcing electronic prior authorization processes across all payer types—including Medicaid, the Children's Health Insurance Program, and the Marketplaces—will reduce administrative burden, enhance transparency, and protect timely access to critical care for children and families.

Children's hospitals frequently manage care for medically complex patients who require subspecialty services across multiple settings, may have multiple coverage sources and may need to travel across state lines for care. These patients are disproportionately affected by care delays resulting from prolonged prior authorization timelines, inconsistent payer requirements, and opaque appeals processes.

We encourage CMS to strengthen this framework by requiring more stringent prior authorization timelines—specifically, no more than 48 hours for standard requests and 24 hours for urgent requests. Payers should also be required to issue clear denial notices that include a clinical rationale, recommended alternatives, and step-by-step instructions for appeal.

Children’s hospitals also routinely treat out-of-state Medicaid beneficiaries who must travel for subspecialty care. These cases often face duplicative prior authorization hurdles across state Medicaid systems. We urge CMS to clarify that the prior authorization and data-sharing standards established under this rule apply equally to out-of-state Medicaid services. In addition, CMS should require payers to honor the requirements in place at the time a request was submitted, rather than applying new rules midstream, and allow for flexibility in the use of CPT code ranges to accommodate pediatric care that may evolve as clinical needs change.

We also support payer-to-payer data exchange requirements and encourage CMS to go further by requiring incoming plans to honor existing authorizations from prior payers for a defined continuity-of-care grace period.

Identification of Duplicative Requirements

• Which specific Medicare requirements or processes do you consider duplicative, either within the program itself, or with other healthcare programs (including Medicaid, private insurance, and state or local requirements)?

Withdraw CoP Regulations that Require Severe Respiratory Illness Reporting (Relevant Regulations: 42 CFR § 482; CMS-1808-F (FY 2025 IPPS Final Rule))

CMS should rescind the new CoP requirement introduced in the CY 2025 IPPS Final Rule that mandates electronic reporting of severe respiratory illness data (e.g., influenza, RSV). Instead, CMS, working with other agencies, as appropriate, should support the infrastructure that hospitals need to voluntarily share acute respiratory illness data with the agencies. This could include flexibility in reporting formats and timelines, recognition of existing pediatric respiratory surveillance systems, and clear guidance that aligns reporting expectations with the capabilities of children’s hospitals.

Rather than establishing a duplicative federal mandate through the CoPs, we recommend that the Department of Health and Human Services coordinate its existing reporting structures (e.g., through the Centers for Disease Control and Prevention) with states, and other stakeholders to strengthen existing surveillance infrastructure and reporting pathways. Children’s hospitals support efforts to monitor critical respiratory illnesses and have long played a central role in managing seasonal surges. However, the new CoP requirements fail to reflect existing reporting structures and the distinct nature of pediatric care, where respiratory illness surveillance infrastructure, clinical variation, workflows and resource constraints often differ significantly from adult systems.

Many children’s hospitals will need to hire and train staff, adjust reporting systems, and divert resources from clinical care. The lack of tailored expectations for pediatric settings risks disrupting care delivery and overburdening hospitals that are already under substantial strain. Federal efforts to track infectious respiratory

disease should focus on supporting children's hospitals with flexible reporting systems that align with real-world pediatric workflows.

- How can Medicare better align its requirements with best practices and industry standards without imposing additional regulatory requirements, particularly in areas such as telemedicine, transparency, digital health, and integrated care systems?

Expand Medicare Coverage of Telehealth and Communication Technology-based Services by Removing Outdated Restrictions (Relevant Regulations: 42 CFR § 410.78)

CMS should revise regulatory restrictions that limit access to telehealth and communication technology-based services, including geographic and originating site requirements and narrow definitions of covered modalities. These constraints hinder how care is safely and effectively delivered and create barriers to access—particularly for pediatric patients in rural and underserved areas.

We urge CMS to support permanent reforms that eliminate geographic and originating site limitations, maintain flexibility in communication modalities, and expand coverage for low-intensity, high-frequency services such as virtual check-ins, asynchronous communications, and interprofessional consultations. These services are vital to ensuring timely, coordinated care for medically complex children and supporting family engagement in care planning and follow-up.

Children's hospitals have long leveraged telehealth to extend specialized care across large geographic regions, especially for children with complex or rare conditions. During the COVID-19 public health emergency, flexibilities in originating site requirements, provider eligibility, and communication modalities—including audio-only—allowed hospitals to maintain care continuity, support family-centered care, and reduce unnecessary travel. These changes were critical for children with multiple chronic conditions, technology dependencies, and limited access to pediatric subspecialists.

The expiration of telehealth flexibilities has reintroduced barriers that disproportionately affect pediatric patients. For example, many children live far from the pediatric subspecialists they need, particularly in rural areas. Returning to in-person originating site requirements forces families to travel long distances—sometimes across state lines—for care that could otherwise be delivered virtually. In particular, children with complex medical needs or technology dependencies, such as those requiring ventilators or feeding tubes, face additional logistical and health risks when traveling for care. In some cases, families must choose between missing school or work and delaying necessary treatment. The loss of audio-only flexibility also affects families without reliable broadband or access to private, quiet spaces for video visits, creating additional barriers to care for low-income and underserved populations.

Permanently Allow Direct Supervision Through Virtual Supervision and Allow Virtual Supervision of Residents for Both Telehealth and In-person Services (Relevant Regulations: 42 CFR § 415.172; 42 CFR § 410.78)

We recommend that CMS permanently adopt virtual supervision flexibilities for all teaching settings, for both telehealth and in-person care, as a modernization that supports the pediatric workforce, improves care coordination, and strengthens access for medically complex children.

The virtual resident supervision flexibilities first implemented during the COVID-19 public health emergency have been particularly valuable for children's hospitals, which continue to face acute staffing shortages amid persistently high demand for inpatient and specialty services. Virtual supervision helps preserve provider capacity by enabling pediatric specialists to support residents remotely while continuing to care for other patients. These tools are especially important in the context of the regionalization of pediatric specialty care, where children may otherwise need to travel long distances to access services. Pediatric patients, especially those with complex or chronic medical conditions, often require coordinated care from multiple subspecialists—some of whom may be located in other regions or states. Allowing residents to provide care—particularly via telehealth—under virtual supervision reduces burdens on both families and providers, while maintaining continuity of care.

Furthermore, the Accreditation Council for Graduate Medical Education provides robust safeguards around the use of virtual supervision to ensure that quality standards are met. Families have reported greater satisfaction and engagement when care is more accessible through virtual means, and residents have benefited from exposure to new, evolving models of pediatric care delivery.

Clarify Regulatory Requirement to Allow Freestanding Children's Hospitals to Participate in the Acute Hospital Care at Home (AHCaH) Programs (Relevant Regulations: 42 CFR § 482.23; CMS §1135 waiver authority; CMS COVID-19 Hospital at Home Waiver (2020))

CMS should create a pediatric pathway for AHCaH eligibility, by extending the existing waiver framework to include freestanding children's hospitals. This change would empower children's hospitals to leverage home-based acute care models in appropriate clinical situations while ensuring oversight and quality standards remain intact.

The COVID-19 public health emergency accelerated innovation in hospital-level care, including the AHCaH model. Unfortunately, freestanding children's hospitals are unable to participate in this model because they are exempt from the Medicare Inpatient Prospective Payment System (IPPS) and, therefore, do not qualify for the Medicare waivers needed to operate HaH programs. The problem is compounded in states that require hospitals to participate in Medicare in order to access similar flexibilities through Medicaid.

This exclusion prevents pediatric hospitals from expanding access to home-based care models with the potential to manage a range of acute conditions in the home such as gastroenteritis, bronchiolitis, neonatal hyperbilirubinemia, cancer, diabetes, and sickle cell disease. HaH programs support children and families by reducing stress, minimizing disruption to school and work schedules, and offers an increased sense of security. Additionally, these programs reduce strain on hospital infrastructures and help ensure that inpatient beds remain available for the children who need them most, particularly during times of increased demand.

Additional Recommendations

Reform Organ Cost Attribution to Sustain Pediatric Transplant Services (Relevant Regulations: 42 CFR § 413 and § 419)

CMS should exempt children’s hospitals from Medicare-only attribution requirements and establish pediatric-specific cost reporting rules for organ procurement. CMS should allow allocation of organ acquisition costs across all payer types for pediatric centers and delay enforcement while updated guidance is developed.

CMS narrowed what counts as reimbursable organ acquisition costs in the FY 2022 IPPS and CY 2023 OPPI Final Rules and tied those costs to Medicare patient attribution. This severely disadvantages pediatric transplant centers, which operate at low volumes and serve mostly non-Medicare patients. Pediatric hospitals often recover organs as part of national organ-sharing efforts by the Organ Procurement Transplantation Network, which matches donated organs to appropriate recipients across the country. In many cases, an organ may be recovered by the children’s hospital and then transplanted into a child patient at another facility who is not enrolled in Medicare. Under the new rules related costs of the organ acquisition, the children’s hospital would be ineligible for reimbursement despite performing a critical function of the transplant process.

Withdraw Separate Hospital Payment Policy for Buffer Stock of Essential Medicines (Relevant Regulations: CMS 1786-FC (CY 2024 OPPI Final Rule))

CMS should withdraw this new policy that pays hospitals separately for the costs of maintaining a buffer stock of essential medicines. Instead, CMS should work with pediatric providers, including children’s hospitals, to develop targeted strategies that support a stable and transparent pediatric drug supply chain.

While intended to prevent shortages, this policy could actually worsen supply issues for pediatric drugs. In particular, this provision could cause a surge in purchasing that would disrupt distribution channels, reduce supply chain transparency, and create shortages of pediatric medications that did not previously exist—particularly disadvantaging children’s hospitals. If a buffer inventory strategy is pursued in future rulemaking, we recommend that inventory only be stored through a central entity to maintain transparency in the process.

It is critical that CMS recognize that ‘essential medicines’ are unique for children compared to adults. The Pediatric Drug List, updated quarterly, identifies drugs essential for pediatric care and differs significantly from adult-focused lists as a result of differences in patient volume and treatment needs due to the significantly smaller number of sick children compared to adults. Pediatric care also relies on specialized therapies and equipment, and the limited number of manufacturers for child-appropriate drugs makes the pediatric supply chain especially fragile. Children’s hospitals already face frequent shortages of essential medications, like albuterol and total parenteral nutrition components. A buffer stock requirement could exacerbate these issues and hinder hospitals’ ability to secure necessary treatments for their child patients.