

#### VIA ELECTRONIC TRANSMISSION

March 13, 2023

The Honorable Xavier Becerra
Secretary of Health and Human Services
U.S. Department of Health and Human Services
200 Independence Avenue SW
Washington, DC 20201

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; Proposed Rule – CMS-0057-P

#### Dear Secretary Becerra:

Thank you for the opportunity to comment on, CMS's Notice of Proposed Rulemaking for prior authorization and interoperability, CMS-0057-P, hereinafter referred to as the "proposed rule." The Georgetown University Center for Children and Families (CCF) is an independent, nonpartisan policy and research center founded in 2005 with a mission to expand and improve high quality, affordable health coverage for America's children and families. As part of the McCourt School of Public Policy, Georgetown CCF conducts research, develops strategies, and offers solutions to improve the health of America's children and families, particularly those with low and moderate incomes through Medicaid and CHIP.

Our comments below are directed at the Medicaid and CHIP provisions of the proposed regulation, but we believe the comments are also generally applicable to Medicare and Qualified Health Plans (QHPs). Current Medicaid and CHIP prior authorization practices lead to unnecessary and harmful delays and disruptions of access to care for children and families. The proposed rule would implement numerous policies that would improve prior authorization processes, such as stronger timelines and reporting requirements. As such, we strongly support the proposed rule and encourage CMS to finalize it, with some

recommendations for improvement detailed below. To the extent they can be implemented without disadvantaging lower-income children and families, we also support many of the proposals to establish or improve interoperability standards across health care coverage programs, with some recommendations for improvement also detailed below.

#### **Prior Authorization**

The proposed rule would strengthen the current requirements relating to prior authorization for both Medicaid and CHIP managed care and fee-for-service (FFS) programs. We support the intent of these proposals—to protect beneficiaries and providers from the use of prior authorization to delay, or deny altogether, access to needed services covered by Medicaid or CHIP—but we believe they do not effectively address the weaknesses in the current requirements. The financial incentives for managed care organizations (MCOs), prepaid inpatient health plans (PIHPs), and prepaid ambulatory health plans (PAHPs) to delay or deny service authorizations are clear: stringent prior authorization controls that result in high rates of denials enable the plan to avoid incurring costs for services, thereby retaining more of its capitation payments. If some beneficiaries and their providers decide to appeal and succeed in overturning the denials, the plan is no worse off, since it is paying for services it was obligated to cover in the first place. The purpose of our recommendations is to ensure that children and families enrolled in Medicaid or CHIP receive the services that they need and are covered by the programs without unnecessary delay.

As proposed, CMS's proposed regulations on prior authorization generally do not apply to prescription drugs (but would apply to drugs furnished as part of other Medicaid benefits like hospital services and nursing home care.) Prescription drugs are a critical component of care that is subject to significant prior authorization, typically tied to whether drugs are on preferred drug lists, and thus could also reduce access to care. We recommend that CMS also apply the regulatory provisions to prescription drugs, except for the provisions on prior authorization timelines (which are already explicitly addressed by section 1927 of the Social Security Act). We believe the best long-term policy is to treat prescription drugs that same as other services for prior authorization purposes.

A. Medicaid and CHIP Beneficiaries Need Greater Protection from Prior Authorization Abuses

While prior authorization may, in limited circumstances tied to evidence-based medicine, improve the safety or efficiency of care, the reality is that in practice it more often leads to delays in care, disruption or abandonment of care, administrative costs, and burden and stress for families and their providers. Furthermore, while electronic prior authorization

and interoperability has the potential to reduce some of the delay and burden association with prior authorization, CMS needs to implement a broader set of changes to prior authorization processes to correct the current abuses that are all too common. Improving the speed of the current prior authorization regime without also addressing the content of prior authorization requests will not improve the harmful outcomes related to widespread inappropriate use of prior authorization processes.

As currently used, prior authorization processes lead to many problems for enrollees and providers. First of all, prior authorization is often overly broad and not based on clinical standards. An OIG report found that some Medicare Advantage prior authorization denials raise concerns about access to medically necessary care.¹ Among Medicare Advantage denials, 13% of denials met Medicare coverage policies and would have likely been approved under original Medicare. The report found that, first, Medicare Advantage plans used clinical coverage criteria that go beyond Medicare coverage rules and resulted in denials of medically necessary services. Second, the Medicare Advantage plans sometimes indicated prior authorization requests did not include sufficient documentation, but review found there was sufficient documentation in the medical record to confirm medical necessity.

Prior authorization is frequently requested for treatments that are high-value or low-risk or otherwise have no compelling clinical basis for requiring prior authorization. For example, prior authorizations used for medications in pediatric hematology and oncology do not alter care or provider benefits, and may negatively impact timeliness of care and patient and family experiences.<sup>2</sup> Prior authorization processes also lead to delays in obstetric imaging.<sup>3</sup> Studies show that prior authorization can limit access to expertly developed standard-of-care treatments.<sup>4</sup> Many patients are denied treatments based on unknown criteria that contradict the conclusions of the medical professional that actually provide their care. Thirty percent of doctors report that prior authorization criteria are rarely or never evidence based.<sup>5</sup> Patients and providers often have no basis to know if prior

<sup>&</sup>lt;sup>1</sup> Office of the Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), <a href="https://oig.hhs.gov/oei/reports/0EI-09-18-00260.pdf">https://oig.hhs.gov/oei/reports/0EI-09-18-00260.pdf</a>.

<sup>&</sup>lt;sup>2</sup> Brad H. Pollock, "Medication Prior Authorization in Pediatric Hematology and Oncology," 64 Pediatric Blood & Cancer 6 (June 2017), <a href="https://doi.org/10.1002/pbc.26339">https://doi.org/10.1002/pbc.26339</a>.

<sup>&</sup>lt;sup>3</sup> Vanita D. Jain, et al., "Prior Authorization and its impact on access to obstetric ultrasound," 222 American Journal of Obstetrics and Gynecology 4 (April 2020),

https://www.sciencedirect.com/science/article/pii/S0002937820300260?via%3Dihub#bib5.

<sup>&</sup>lt;sup>4</sup> "Vital Access: How Policymakers Can Streamline the Cancer Care Journey," Leukemia & Lymphoma Society (Jan. 2023), https://www.lls.org/sites/default/files/2023-01/vitalaccess2023.pdf.

<sup>&</sup>lt;sup>5</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a>.

authorization criteria are properly designed and applied. At their worst, prior authorization processes subject to terrible abuses that hurt enrollees.<sup>6</sup>

Medicare Advantage data raises grave concerns about how prior authorization is in fact being used. A Kaiser Family Foundation review of Medicare Advantage data found that only 11% of the 2 million prior authorization denials in 2021 were appealed. However, a vast majority (82%) of the appeals resulted in a full or partial overturning of the denial. This data implies that an incredible number of prior authorization requests that were denied might have been denied improperly, and might have been approved if only reviewed on appeal.

In other cases, the prior authorization requirements are strictly an effort to reduce access to expensive treatments, irrespective of their clinical appropriateness and the underlying diagnosis. Treating physician specialists are often overruled by providers who have never met the patient and lack the expected subspecialization. One example is a 22-year old man who, shortly after he was born, was diagnosed with severe cerebral palsy. He has a gastronomy tube and a tracheostomy and is unable to walk, communicate verbally, clear his airway, or perform any activities of daily living. Due to his severe disabilities, he requires 24/7 skilled nursing care. He is enrolled in Medicaid, which has covered 168 hours of skilled care per week to enable him to live at home instead of in an institution, since 2006. In 2020, his physician wrote a renewal order for 168 weekly hours; the MCO denied the request, reducing the number of hours covered to 140 per week on the grounds that 168 hours were no longer medically necessary. The parents appealed, and the MCO increased its authorization to 150 hours per week. The parents appealed again, but the MCO, relying on the advice of a consulting obstetrician-gynecologist, refused to restore the full 168 hours per week. Before the reduction in hours could take effect, the COVID-19 public health emergency intervened, but with the unwinding of the continuous eligibility provisions, this beneficiary and his family are again at risk of a reduction in needed services.

In many instances, prior authorization is denied (or not approved) despite the plan or state having all the information needed to make a decision, including situations where the

<sup>&</sup>lt;sup>6</sup> David Armstrong, et al., "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings," ProPublica (Feb. 2, 2023), <a href="https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis">https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis</a>.

<sup>&</sup>lt;sup>7</sup> Jeannie Fuglestwn Biniek et al., "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021," Kaiser Family Foundation (Feb. 2, 2023), <a href="https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021">https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021</a>.

information may have been shared by the provider or available in the medical record.<sup>8</sup> Providers often need to make multiple efforts to contact plans or states, and when they do their staff spend long periods of time to obtain approvals. This costs providers time and resources. In 2018, health care providers spent \$528 million on prior authorization administration, including 21 minutes of staff time per prior authorization.<sup>9</sup> The prior authorization process creates tremendous burden for physicians, including 41 prior authorizations per physician per week that occupy almost two days per week of work.<sup>10</sup> Forty-eight percent of physicians have staff who exclusively work on prior authorization, and 88% of physicians describe the prior authorization burden as high or extremely high.<sup>11</sup> As a result, prior authorization processes are a leading source of job dissatisfaction for physicians.<sup>12</sup>

Beneficiaries are also harmed by the process. Beneficiaries can suffer psychological harm and trauma trying to fight through prior authorization processes, while *already* struggling with a health problem. <sup>13</sup> This includes serious problems for parents trying to navigating the prior authorization process on behalf of their young children. <sup>14</sup> In addition, a majority of physicians report that prior authorization has interfered with a patient's ability to perform their job. <sup>15</sup>

Most importantly, prior authorization processes result in worse care and outcomes. Many individuals end up with long delays before receiving treatment or receive no treatment at all – often resulting in worse outcomes or increased cost. One study showed that a prior authorization policy for diabetes medications increased overall costs for individuals denied based on prior authorization, relative to individuals that had no prior authorization

<sup>&</sup>lt;sup>8</sup> Office of the Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care," https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf.

<sup>&</sup>lt;sup>9</sup> "Conducting Electronic Business Transactions: Why Greater Harmonization Across the Industry is Needed," 2019 CAQH Index (2020), <a href="https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf">https://www.caqh.org/sites/default/files/explorations/index/report/2019-caqh-index.pdf</a>.

<sup>&</sup>lt;sup>10</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a>.

<sup>11</sup> *Id.* 

<sup>&</sup>lt;sup>12</sup> "Sources of physician satisfaction and dissatisfaction and review of administrative tasks in ambulatory practice: A qualitative analysis of physician and staff interviews," American Medicaid Association (Oct. 2016), <a href="https://www.ama-assn.org/media/13506/download">https://www.ama-assn.org/media/13506/download</a>.

<sup>&</sup>lt;sup>13</sup> David Armstrong, et al., "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings," ProPublica (Feb. 2, 2023), <a href="https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis">https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis</a>.

<sup>&</sup>lt;sup>14</sup> Carolyn Y. Johnson, "I wrote about high-priced drugs for years. Then my toddler needed one," Washington Post (Jan. 30, 2023), <a href="https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies">https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies</a>.

<sup>&</sup>lt;sup>15</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a>.

limiting their access to the medication. <sup>16</sup> A survey of physicians found that over half (56%) reported that prior authorization "often" or "always" delays access to necessary care and more than one-third reported that prior authorization led to a serious adverse event, including hospitalizations, disability or even death. <sup>17</sup> A large majority (88%) of providers surveyed also report that prior authorization interferes with the continuity of ongoing care. <sup>18</sup> Overall, 91% of doctors view prior authorization as having a negative impact on clinical outcomes, with just 7% saying it has no impact and only 1% believing it has a positive impact. <sup>19</sup>

After making numerous unsuccessful efforts, many patients or their providers may simply give up on the prescribed treatment – abandonment is a common result of prior authorization process. About four in five doctors report that prior authorization can "sometimes" or "often" lead to treatment abandonment.<sup>20</sup> Another study showed that a prior authorization policy implemented on Medicaid beneficiaries with bipolar disorder led to significant treatment discontinuation, with only minimal switching to lower cost drugs or savings.<sup>21</sup>

During the COVID-19 public health emergency, some states limited prior authorization processes for all or certain services. This helped ease access to needed treatment but also led to an increase in managed care audits of treating providers. Audits can be an incredibly burdensome and time-consuming process for Medicaid/CHIP providers. We recommend that CMS use this regulation as an opportunity to address some of these serious and long-standing problems with the prior authorization process while also maintaining strong oversight over post treatment audits and recoupments.

#### B. Timeframes for Prior Authorization Decisions

1. Medicaid managed care (§438.210(d))

<u>Proposal.</u> The proposed rule would require that MCOs, PIHPs, or PAHPs provide notice of a decision on a standard authorization within a state-established timeframe that does not

<sup>&</sup>lt;sup>16</sup> Joette Gdovin Bergeson, et al., "Retrospective database analysis of the impact of prior authorization for type 2 diabetes medications on health care costs in a Medicare Advantage Prescription Drug Plan population," Journal of Managed Care Pharmacy (June 2013), <a href="https://www.ncbi.nlm.nih.gov/pubmed/23697475">https://www.ncbi.nlm.nih.gov/pubmed/23697475</a>. <sup>17</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a>.

<sup>&</sup>lt;sup>18</sup> "Measuring progress in improving prior authorization," American Medicaid Association (2021 Update), <a href="https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf">https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf</a>.

<sup>&</sup>lt;sup>19</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

<sup>&</sup>lt;sup>21</sup> Yuting Zhang, "Effects of prior authorization on medication discontinuation among Medicaid beneficiaries with bipolar disorder," Psychiatric Services (April 2009), <a href="https://pubmed.ncbi.nlm.nih.gov/19339328">https://pubmed.ncbi.nlm.nih.gov/19339328</a>.

https://apps.legislature.ky.gov/recorddocuments/bill/23RS/HB134/HCS1.pdf.

exceed seven calendar days after receiving a request for services (rather than the current 14 calendar day timeframe). It would leave in place the current policy that permits an extension of this standard authorization timeframe to up to an additional 14 calendar days if (1) the enrollee or the provider requests the extension or (2) the MCO, PIHP, or PAHP justifies (to the state Medicaid agency upon request) a need for additional information and how the extension is in the enrollee's interest.

With respect to expedited authorization decisions, the proposed rule would maintain the current timeframe of 72 hours as an outer bound but allow for a shorter minimum time frame if "established under State law." The proposed changes would be effective for all risk contracts with MCOs, PIHPs, or PAHPs that apply to rating periods starting after January 1, 2026.

The proposed rule would not modify the current requirements at §438.210(c), requiring plans to provide notice of decisions to deny a service authorization request or to limit the amount, duration, or scope of the service requested.

Comment. We agree that the timeframe for standard authorization requests should be reduced but believe that the seven-day outer bound does not sufficiently protect beneficiaries against unnecessary delays in accessing services, particularly given the increased interoperability and prior authorization Application Programming Interfaces (API) that are also being implemented. We also do not believe that the additional 14-day limit on extensions of the standard authorization is warranted, particularly when the MCO, PIHP, or PAHP has the ability to invoke the extension without a justification unless the state agency requests a justification. This enables the MCO, PIHP, or PAHP to burden providers and beneficiaries with requests for additional information and wait an additional 14 days before denying (or approving) the service request in whole or in part.

As to expedited authorization requests, the current 72-hour timeframe is excessive, considering the urgent circumstances under which expedited requests are sometimes made and the implementation of interoperable systems and eventually Prior Authorization Requirements, Documentation, and Decision (PARDD) APIs.

Recommendation: Revise §438.210(d) to require that MCOs, PIHPs, and PAHPs respond to requests for services under a standard authorization within 48 hours of receipt of the request, unless the provider or the beneficiary seeks an extension, in which case the timeframe should be no longer than seven calendar days from the receipt of the initial request. The response to the request for services should take the form of a notice to the beneficiary and the treating provider that meets the requirements of §438.210(c).

With respect to requests for expedited authorizations—i.e., those in which the provider indicates, or the MCO, PIHP, or PAHP determines, that following the standard authorization timeframe would seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain function—revise §438.210(d) to require a response within 24 hours of receipt, with no provision for an extension unless the provider or enrollee requests an extension for up to a total of 72 hours of the initial request. The response to the request for services should take the form of a notice to the beneficiary and the treating provider that meets the requirements of §438.210(c).

### 2. Medicaid Fee-for-Service (§440.230(e))

<u>Proposal.</u> Current regulations do not contain provisions relating to the use of prior authorization in Medicaid FFS programs. The proposed rule would establish timeframes for state Medicaid agencies administering FFS programs for all prior authorization decisions involving requests for items and services other than prescription drugs, effective January 1, 2026.

The timeframe for standard authorization requests would be no greater than seven calendar days from receipt of the request unless a shorter minimum timeframe is established under state law. This timeframe could be extended by up to 14 days if the beneficiary or provider requests an extension, or if the state agency determines that additional information from the provider is needed to make a decision.

The timeframe for an expedited determination would be as expeditiously as a beneficiary's health condition requires, but in no case longer than 72 hours from receipt of the request unless a shorter timeframe is established under state law.

The state agency would be required to provide the beneficiary (but not the provider) with notice of its prior authorization decision per §435.917. It would also be required to provide fair hearing rights for beneficiaries to challenge denials or partial denials of services requested.

<u>Comment</u>. We support the proposed inclusion of protections for beneficiaries in FFS Medicaid programs from unnecessary delays in access to needed services due to prior authorization requirements. However, the proposed timeframes are excessive, the criteria for an expedited determination are inadequate, the notice requirements are insufficient, and the consequences of an agency not meeting the timeframes are unclear. In our view, prior authorization policies and processes, including timelines, should be aligned between FFS and managed care.

Medicaid beneficiaries and their providers should not face different prior authorization timeframes depending on the delivery system.

Recommendation. Revise §440.230(e) to conform to the timeframes recommended above for MCOs, PIHPs, and PAHPs—i.e., 48 hours for a standard authorization, with an extension (if requested by the beneficiary or provider) of up to seven calendar days from the receipt of the initial request, and 24 hours for an expedited authorization, with an extension (if requested by the beneficiary or provider) of up to 72 hours from the receipt of the initial request.

Revise §440.230(e)(1)(ii) to conform to §438.210(d)(2)(i) by striking "For an expedited determination" and inserting "For cases in which a provider indicates, or the state agency determines, that following the standard timeframe could seriously jeopardize the enrollee's life or health or ability to attain, maintain, or regain maximum function, the agency must make an expedited authorization decision" before "as expeditiously as a beneficiary's health condition requires...."

Clarify that failure of the agency to make a decision on a standard or extended authorization within the specified timeframes constitutes a denial and is thus an adverse benefit determination on the date the timeframe expires, triggering a right to a fair hearing. This will align fee-for-service with current managed care policy at \$438.404(c)(5).

Revise §440.230(e)(2) to require the state Medicaid agency to provide notice of a decision on an authorization request (standard or expedited) to the provider as well as the beneficiary. The contents of the notice should be the same as those required of MCOs, PIHPs, and PAHPs under §438.404(b) with the exception of the requirements, inapplicable to FFS, such as those relating to the one level of appeal within the MCO, PIHP or PAHP.

# 3. CHIP Managed Care (§457.1230(d))

<u>Proposal</u>. The proposed rule would maintain the current policy that requires separate state CHIP programs that use managed care to deliver services to ensure through its risk contracts that each MCO, PHIP or PAHP complies with the Medicaid requirements for coverage and authorization of services at §438.210.

<u>Comment</u>. We support alignment of beneficiary protections in CHIP and Medicaid managed care, including those relating to decisions on service authorization requests.

Recommendation: Maintain §457.1230(d) as proposed, applying §438.210 to CHIP managed care as modified by the recommendations for stronger beneficiary protections made in these comments.

# 4. CHIP Fee-for-Service (§457.495(d))

<u>Proposal</u>. The proposed rule would require that prior authorization decisions be completed in accordance with the medical needs of the patient not later than seven calendar days after receiving the request for a standard determination (rather than the current 14 days). Expedited determination requests would have to be decided no later than 72 hours after receipt (there is currently no provision for such requests). In either case, the proposed rule would allow an extension of an additional 14 days if (1) the enrollee requests the extension or (2) the physician or health plan determines additional information is needed. The proposed rule applies these timelines to outpatient prescription drugs as with other items and services.

<u>Comment</u>. Children enrolled in CHIP FFS should have the same protections against unnecessary delays in access to needed services due to burdensome prior authorization procedures, and the same notice rights relating to state agency decisions, as children enrolled in CHIP managed care and Medicaid.

Recommendation. Revise §457.495(d) to require state CHIP agencies to follow the same rules as apply to state Medicaid agencies under §440.230(e), modified as recommended above, and to require response to prior authorization requests for outpatient prescription drugs to be consistent with the policies, including timelines, applicable in CHIP managed care and Medicaid (i.e., aligned with §457.1230 and § 438.210.

#### C. Other Prior Authorization Protections

#### 1. Duration of Prior Authorization Decisions

<u>Proposal</u>: Current regulations do not specify the length of time that a decision by an MCO, PIHP, or PAHP to approve a request for authorization of a service should apply. The proposed rule does not address this issue.

<u>Comment</u>: Current regulations allow MCOs, PIHPs, or PAHPs to limit the time period of an authorization for a service and to require the provider and beneficiary to submit a new request for authorization as frequently as the MCO, PIHP, or PAHP decides is in the organization's interest. In cases where the beneficiary's health condition has not changed since the approval of the initial authorization request, the requirement for a new

authorization is an unwarranted burden on the provider that creates a risk of disruption in the course of treatment for the beneficiary.

Recommendation: Revise the Medicaid prior authorization requirements for managed care at §438.210(d) and for fee-for-service at §440.230(d), including for prescription drugs, to specify that the approval of a standard request for authorization of a service is valid for a minimum period of 6 months unless the MCO, PIHP, or PAHP documents to the satisfaction of the state Medicaid agency that there has been sufficient improvement in the health condition of the enrollee that was the basis for the initial approval that a new authorization decision is warranted.

Revise the CHIP coverage and authorization requirements for managed care at §457.1230(d)) and FFS at §457.495(d) to align them with Medicaid by cross-reference.

### 2. Transparency of Criteria for Authorization Decisions

<u>Proposal</u>: Current Medicaid managed care regulations at §438.210(a)(4) require that risk contracts permit an MCO, PIHP, or PAHP to place "appropriate" limits on a service either on the basis of criteria applied under the state's Medicaid plan or for purposes of utilization control. In addition, the regulations at §438.210(b) currently require that the MCO, PIHP, or PAHP have in effect "a mechanism to ensure consistent application of review criteria for authorization decisions." The regulations do not, however, require MCOs, PIHPs, or PAHPs to post the review criteria they apply in deciding standard or expedited authorizations. The same is true for prior authorization review criteria in Medicaid FFS and in CHIP managed care and FFS. The proposed rule would leave these policies unchanged.

Comment: Without the criteria that an MCO, PIHP, PAHP, or state Medicaid or CHIP agency will apply to a standard or expedited request for authorization, it is simply not possible for the treating provider to know what information will be relevant to the decision. This can result in unnecessary delays due to requests for more information by the MCO, PIHP, PAHP or state agency, creating unnecessary delays in the decision. Under the current managed care regulations at §438.404(b)(2), enrollees have a right to information about an adverse decision, including "medical necessity criteria" and "any processes, strategies, or evidentiary standards used in setting coverage limits," but only after their authorization request has been denied. If prior authorization is to be a tool for educating providers and beneficiaries about the limits of coverage, rather than a mechanism for delay and arbitrary denials that have to be appealed, it is in the interests of the state, the providers, and the beneficiaries that the plans be transparent about their review criteria.

Recommendation: Revise the Medicaid managed care regulations at §438.210(b) to require that MCOs, PIHPs, and PAHPs post in a prominent location on their websites all of the review criteria they or their subcontractors use to make standard and expedited authorization decisions, including for prescription drugs, regardless of whether the MCO, PIHP, PAHP or subcontractor considers the criteria to be proprietary. Under a previous recommendation, the CHIP managed care regulation at §455.1230(d) will align by cross-reference. State Medicaid and CHIP agencies that operate FFS programs and their utilization management vendors should be subject to the same transparency requirements.

3. Prior Authorization and Early and Periodic Screening, Diagnostic and Treatment (EPSDT) Services

<u>Proposal</u>: Current Medicaid regulations at §438.210(a)(5) require that the risk contract with an MCO, PIHP, and PAHP specify what constitutes "medically necessary services" in a manner that is no more restrictive than that used in the state Medicaid program. The contract must also address the extent to which the MCO, PIHP, or PAHP is responsible for covering services that address, among other things: the prevention, diagnosis, and treatment of an enrollee's disease, condition, and/or disorder; the ability for an enrollee to achieve age-appropriate growth and development; and the ability for an enrollee to attain, maintain, or regain functional capacity. The proposed rule would make no change in this requirement.

Comment: In the case of EPSDT services for children under 21, the Medicaid statute at section 1905(r)(5) specifies a standard for "medically necessary services" that is intentionally broader than the usual commercial standard: "such necessary health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services." As a recent letter from the Florida Commissioner of Child Welfare Services to the Director of the state Medicaid program demonstrates, state risk contracts with MCOs, PIHPs, and PAHPs do not consistently specify this statutory "medically necessary" standard for EPSDT services and, as a result, managed care plans use more restrictive criteria to deny authorization for services to which children are entitled under EPSDT.<sup>23</sup>

Recommendation: Revise §438.210(a)(5) to require that, with respect to EPSDT services for children under 21, a risk contract with an MCO, PIHP, or PAHP specify that "medically necessary services", including prescription drugs, are "such necessary

12

<sup>&</sup>lt;sup>23</sup> Letter from Commissioner Candice Broce, Georgia Department of Human Services, to Commissioner Caylee Noggle, Georgia Department of Community Health, August 12, 2022, <a href="https://www.documentcloud.org/documents/23577647-broceletter202208">https://www.documentcloud.org/documents/23577647-broceletter202208</a>.

health care, diagnostic services, treatment, and other measures described in section 1905(a) to correct or ameliorate defects and physical and mental illnesses and conditions discovered by the screening services."

Revise §438.210(b) to require that an MCO, PIHP, or PAHP responsible for delivering EPSDT services to children under its risk contract apply the EPSDT-specific "medically necessary" standard in such a manner that the following are exempt from a requirement for prior authorization: (1) all screening services described in §441.56(b) and (2) all diagnostic or treatment services, including prescription drugs, on behalf of children whose need for the services or treatment has been discovered by a screening service under section 1905(r)(5) of the Social Security Act. A state may require prior authorization (consistent with the timeframes in §438.210(d) and §440.230(e)) with respect to diagnostic or treatment services the need for which has been discovered by a screening service if the Secretary determines, based on clinical evidence, that furnishing the service without prior authorization is likely to result in harm to children.

# 4. Prior Authorization and Maternity Care.

<u>Proposal</u>: The proposed rule would not change the application of prior authorization requirements to maternity care services.

<u>Comment</u>: As noted in the preamble to the proposed rule, prior authorization can have negative impacts on maternal care.<sup>24</sup> Some insurance companies require prior authorization for prenatal testing that expert medical groups recommend as the standard of care for all pregnancies.<sup>25</sup> Unlike other areas of care, prescribed maternity care services are almost always time-sensitive. We are not aware of any data suggesting that maternity care has high volumes of overprescribing or cost associated to overprescribing.

Recommendation: CMS should exclude maternity care services (including perinatal, labor and delivery, and postpartum services), including prescription drugs, from prior authorizations. If CMS does not prohibit prior authorization for maternity care services, then we recommend that CMS adopt two additional policies. First (consistent with our recommendation for EPSDT above), the Secretary, based on evidence, should

<sup>&</sup>lt;sup>24</sup> Vanita D. Jain, et al., "Prior Authorization and its impact on access to obstetric ultrasound," 222 American Journal of Obstetrics and Gynecology 4 (April 2020),

https://www.sciencedirect.com/science/article/pii/S0002937820300260?via%3Dihub#bib5.

<sup>&</sup>lt;sup>25</sup> Brianna Wetherbe, "Opinion: Prior Authorization Imposes Unnecessary Barriers to Prenatal and Maternal Care," Times of San Diego (July 14, 2021), <a href="https://timesofsandiego.com/opinion/2021/07/14/opinion-prior-authorization-imposes-unnecessary-barriers-to-prenatal-and-maternal-care">https://timesofsandiego.com/opinion/2021/07/14/opinion-prior-authorization-imposes-unnecessary-barriers-to-prenatal-and-maternal-care</a>.

identify medications and treatments that pose a risk to the health of pregnant or postpartum individuals and limit state use of prior authorization to those services under the circumstances identified by the Secretary. Second, we recommend that CMS establish stronger timeline standards to ensure prompt access to care. All maternity care prior authorization requests should be deemed "expedited" (under our recommendations, requiring a response within 24 hours) and any non-response within the required timeframe should be deemed an approval. In addition, CMS should allow that any response from a state or plan that is not an approval (for example a request for more information), can be treated as a denial at the choice of the patient or provider (such that they can proceed directly to an appeal).

## D. Reporting of Authorization Decisions

1. MCO, PIHP, and PAHP reporting and transparency requirements (§438.210(f))

<u>Proposal.</u> The proposed rule would require each MCO, PIHP, and PAHP to report by March 31 specified data on prior authorization decisions made by the plan during the prior calendar year. The MCO, PIHP, or PAHP would also be required to post the specified data directly on its website or make it accessible via hyperlink(s). The requirement would be effective January 1, 2026.

Comment: We strongly support the proposed requirement that MCOs, PIHPs, and PAHPs report and post data on Medicaid prior authorization decisions. (We speak to the specified data elements below). This will enable all stakeholders, including state Medicaid officials, CMS, network providers, and the public, to understand what results each individual MCO or PIHP or PAHP's prior authorization system is producing and to compare the performance of all the plans contracting with the state. We also support applying this requirement to MCOs, PIHPs, and PAHPs contracting with separate state CHIP programs, which we understand to be the proposal by virtue of the cross-reference to the terms of §438.210 in §457.1230(d). We have some recommendations for clarifying the proposed language to avoid any misunderstandings on the part of plans or state agencies. We recommend that all reporting include prescription drug data as well.

Recommendation: Revise §438.210(f) to clarify that: (1) the report required of each MCO, PIHP, or PAHP must be submitted to the state Medicaid (or CHIP) agency with which the plan has a risk contract; (2) the first report is due March 31, 2026, with respect to prior authorization decisions made by the plan during calendar year 2025; and (3) the March 31 deadline applies to both the submission of the report to the state and to the posting of the prior authorization data directly or via hyperlink(s) on the plan website.

2. State Medicaid and CHIP agency reporting and transparency requirements (§440.230(f), §457.732(c))

<u>Proposal</u>. The proposed rule would require both state Medicaid agencies and state CHIP agencies to report by March 31 of each year specified prior authorization data for the previous calendar year. The specified data would be at the state, not the plan level. The proposed rule would also require the state agency to post the specified data directly on its website or via hyperlinks. These requirements would be effective beginning in 2026.

Comment. We strongly support the proposal to require state Medicaid and CHIP agencies to report prior authorization data on an annual basis and make that data publicly available. (We comment on the specific data elements below). We do not, however, believe that state-level data, by itself, is useful for understanding how individual MCOs or PIHPs or PAHPs are using prior authorization and how their use of prior authorization is affecting timely access of beneficiaries to needed services. State-level prior authorization data can provide important context for prior authorization data from individual MCOs or PIHPs or PAHPs; making both state- and plan-level data publicly available on the state agency website will be valuable to all stakeholders.

Recommendation: Revise both §440.230(f) and §457.732(c) to require that state Medicaid and CHIP agencies report both state- and plan-level prior authorization data to CMS and post both state-level and plan-level prior authorization data on the agency website, directly or by hyperlink(s). Because MCOs, PIHPs, and PAHPs would not be required to report their data to the state agency until March 31, extend the deadline for reporting to CMS and posting of this data by state agencies to May 31.

Revise both §440.230(f) and §457.732(c) to clarify that: (1) the report required of the state must be submitted to CMS; (2) the first report to CMS is due May 31, 2026, with respect to prior authorization decisions made by the plans during calendar year 2025; and (3) the May 31 annual deadline (see above) applies to both the submission of the report to the state and to the posting of the prior authorization data directly or via hyperlink(s) on the plan website.

3. Prior Authorization Data (§438.210(f)), §440.230(f), §457.732(c))

<u>Proposal</u>: The proposed rule specifies nine data elements for reporting and posting by both individual MCOs, PIHPs, and PAHPs and by state Medicaid and CHIP agencies: (1) a list of items and services subject to prior authorization; the percentage of standard authorization requests (2) approved, (3) denied, and (4) approved after appeal; the percentage of

expedited prior authorization requests (5) approved and (6) denied; (7) the percentage of prior authorization requests for which the review timeframe was extended and the request was approved; and the average and median time elapsed between submission of the request and a determination for (8) standard prior authorizations and (9) expedited prior authorizations. In all cases, the percentages would be aggregated for all items and services, and data on any and all drugs covered by the state Medicaid or CHIP program would be excluded.

Comment: We strongly support annual reporting of prior authorization data and the posting of that data. We support the proposed rule's requirement that in managed care states, reporting and posting be plan-specific. We also support the proposed rule's requirement that the data elements to be reported and posted be aligned between Medicaid and CHIP and among managed care and FFS states. If our recommendations relating to shortening the timeframes for standard and expedited authorization decisions are adopted, items (7), (8), and (9) above would be unnecessary.

The data elements specified by the proposed rule do not align with the data elements currently required to be reported for appeals (on a plan-specific basis) in the excel workbook for the <u>Annual Managed Care Program Report</u> (MCPAR) that states are required to submit to CMS under §438.66(e). Among other things, the MCPAR reporting template specifies that the number, not just percentages, of requests and appeals be reported; that they be disaggregated by broad service categories (e.g., general inpatient services, inpatient behavioral health services, etc.); and that they include the results of State Fair Hearings. Without alignment, it will not be possible for stakeholders to assess the impact of an MCO, PHIP, or PAHP's prior authorization determinations on beneficiary access to requested services.

Recommendation: Revise §438.210(f), relating to the prior authorization data that each MCO, PIHP, and PAHP must publicly report, and §440.230(f) and §457.732(c), relating to the data that state Medicaid and CHIP agencies, respectively, must publicly report, to specify the following data for the previous calendar year:

- (1) A list of all items and services that require prior authorization;
- (2) The number of standard prior authorization requests that were made, the number that were approved, and the number that were denied;
- (3) The number of standard prior authorization requests that were appealed, and the number that were approved after appeal;
- (4) The number of standard prior authorization requests in which, after appeal, an adverse benefit determination is upheld and a State Fair Hearing is requested, and the number of standard prior authorization requests that were approved after a State Fair Hearing; and
- (5) The number of expedited prior authorization requests that were made, the number that were approved, and the number that were denied.

In each instance, the data must be disaggregated by the following service categories: general inpatient services; general outpatient services; inpatient behavioral health services; outpatient behavioral health services; covered outpatient prescription drugs; skilled nursing facility services; long-term services and supports; dental services; non-emergency medical transportation services; and other service types.

# **Fair Hearings, Notice, and Due Process** (§§ 431.201, 431.220, and 435.917)

<u>Proposal</u>: The proposed regulation would add language to codify CMS's current policy which requires full Medicaid due process for prior authorization denials. The proposed rule adds prior authorization processes to the list of Medicaid Fair Hearing topics and the "actions" that can be appealed with continuing benefits. It also clarifies some language in the regulation.

<u>Comment</u>: We broadly support HHS's intent to clarify in the regulatory text that Medicaid due process applies to prior authorization processes. It is critical for CMS to improve due process around prior authorization. Evidence from Medicare Advantage, where only 11% of prior authorization denials are appealed despite an 82% success rate on appeal, suggests that prior authorization appeals have a critical role to play across health care programs.<sup>26</sup>

Recommendation: Specifically, we strongly support the addition of prior authorization to the Fair Hearing list in §431.220 and the proposed added language and updated headings in §435.917. We also support the reorganization of §431.201 to clarify the definition of "action."

We recommend that HHS consider notice and appeal rights more broadly with respect to prior authorization. When advancing the use of APIs and other communication systems, HHS should consider whether and how notice and appeal rights can be satisfied through electronic formats. This is of particular concern for lower income consumers who may lose access to electronic sources when a phone is lost or internet service is discontinued. We recommend that HHS continue to require a redundant written notice for all important notices (including for prior authorization), including denials, partial denials, eligibility changes, and notices requiring follow-up action.

We also recommend that CMS develop policies to address how notice about prior authorization denials is provided at point of service. When consumers receive notice of

<sup>&</sup>lt;sup>26</sup> Jeannie Fuglestwn Biniek et al., "Over 35 Million Prior Authorization Requests Were Submitted to Medicare Advantage Plans in 2021," Kaiser Family Foundation (Feb. 2, 2023), <a href="https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021">https://www.kff.org/medicare/issue-brief/over-35-million-prior-authorization-requests-were-submitted-to-medicare-advantage-plans-in-2021</a>.

denial and appeal rights after the fact it creates numerous barriers to them responding to the denial. We anticipate this will become a significant issue as the proposed APIs (particularly the PARDD API) begin to function. If consumers receiving real-time prior authorization results at office visits could receive notice of their rights at their visit, they could discuss their options (including treatment alternatives or filing an appeal) with their provider. If they receive notice in the mail at a later date, consumers cannot efficiently resolve the matter, and may in some cases not even know what the denial refers to. Point of service notice is a particular area of concern at pharmacies. Consumers filling prescriptions should leave the pharmacy with either their prescription or a notice of denial spelling out their rights.

# **Communication with Providers** (§§ 431.80, 438.242, 457.732)

<u>Proposal</u>: The proposed regulation would require states to respond to provider requests (except for those relating to prescription drugs) and, if a state denies a request, include "a specific reason for the denial" in the response.

Recommendation: We strongly support requirements across programs to communicate prior authorization statuses to providers, including a specific reason for denial. CMS should consider developing requirements for specificity on the reason for denial, including clear and actionable next steps. For example, if some piece of documentation was missing, that should be specified. In particular, "medical necessity" denials can cover a wide range of potential factors, and states should be required to provide a more granular response than "failure to establish medical necessity." It is important for providers to know why a prior authorization was denied and what steps could secure and approval. In Medicare Advantage, the Office of the Inspector General found that prior authorization policies may exceed the program coverage criteria providers know about and denials may in fact be based on needing documentation which is already in the medical file.<sup>27</sup>

We also recommend that CMS include prescription drugs in this requirement. We are not aware of any reasons why providers could not be informed of prescription drug prior authorization results and we believe the information would be equally important for medications.

## **Application Programming Interfaces**

<sup>27</sup> Office of the Inspector General, "Some Medicare Advantage Organization Denials of Prior Authorization Requests Raise Concerns About Beneficiary Access to Medically Necessary Care" (April 2022), <a href="https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf">https://oig.hhs.gov/oei/reports/OEI-09-18-00260.pdf</a>.

## A. APIs Generally

<u>Proposal</u>: The proposed rule would require states and health plans to add prior authorization to existing Patient Access APIs, as well as create three new types of APIs: Provider APIs, Payer-to-Payer APIs, and PARDD APIs. These APIs would allow increased communication among patients, providers, and plans, that should facilitate timely and well-coordinated care. The proposed regulation exempts prescription drug information from inclusion in the APIs. The proposed API changes would be effective January 1, 2026 (or plan years beginning after that date).

Recommendation: We are broadly supportive of CMS's effort to advance the use of APIs, including the new Provider, Payer-to-Payer, and PARDD APIs. APIs will give consumers and their providers more access to timely information and will reduce burdens on consumers and providers alike. Furthermore, because prior authorization processes heavily impact health care access and are an important part of health records, we support the inclusion of prior authorization information in all APIs.

More specifically, we strongly support the required inclusion of prior authorization details, such as the specific reason for denials. Consistent with our recommendation above (see Communication with Providers), we recommend that CMS develop requirements for the specificity required in the "specific reason why the request was denied."

We recommend that CMS include prescription drugs in all APIs. We are not aware of any important reason why this is not feasible and we believe the information critically important to advance well-coordinated, high-quality health care.

We also recommend that CMS consider if and how the transfer of sensitive parts of medical records through the API could be suppressed upon patient request. Without such a mechanism, using an API might be an "all or nothing" choice that some consumers will reject out of concern for their privacy regarding a specific diagnosis or treatment. Enabling the suppression of sensitive data fields will not impact the large majority of consumers who will not choose to suppress any parts of their records in an API.

Below, we provide additional comments to specific APIs.

B. Patient Access API (§§ 431.60, 438.242)

Recommendation: We support the requirement for reporting on Patient API usage. This will be important to assess take up of API usage and how APIs are being used and adding value. To truly understand the value of how APIs are being used and how they are improving access for different subpopulations, we urge CMS to require reporting with granularity based on all of the demographic information feasible (for example, at a minimum, claims forms should allow managed care plans to report by age, gender, and zip code).

We recommend that CMS further clarify how API access will be handled for children, including children in foster care, as well as family caregivers. CMS should also broadly ensure that individuals who do not have access to software or apps are not disadvantaged because they do not use an API. If any important notice is provided or response required via an API, such as an app accessing a Patient API, CMS should require states continue to provide redundant written methods of notice for individuals. Individuals may not understand notice is being provided electronically, and lower income consumers may be unable to quickly repair or replace a phone that is lost or damaged, or may lose their cellular or data access.

#### C. Provider Access API (§§ 431.61, 438.242)

Recommendation: We support the requirement to provide information to beneficiaries in simple language about Provider Access APIs and their right to opt out of participation. We believe that few enrollees will choose to opt out, but the right to opt is important to protecting the autonomy and confidentiality of enrollees.

We do not support the specific provisions allowing extensions for Medicaid and CHIP FFS programs. With respect to exemptions in states with low FFS rates, we recommend CMS raise the exemption threshold to 95% managed care participation and phase out the exemption entirely after two years. In many states some of the most clinically complex consumers remain in FFS programs and these may be the enrollees that most benefit from Provider Access APIs.

# D. Payer-to-payer API (42 C.F.R. §§ 431.61, 438.242)

Recommendation: We support the requirement to provide educational materials and information to beneficiaries in simple language about APIs and their right to opt  $\underline{in}$  to participation. Transitions to new managed care plans are not as frequent as provider-to-provider interaction, and managed care plans can ensure opt-in authorization is collected. We are concerned that the cross-references in the proposed regulation for Medicaid managed care at §438.242(b)(7) do  $\underline{not}$  include reference to the opt-in provisions

 $\S431.61(b)(2)$ . If this omission was intentional, we reiterate our recommendation for the adoption of an opt-in mechanism for Medicaid managed care.

We do not support the specific provisions allowing extensions for Medicaid and CHIP FFS programs. With respect to exemptions in states with low FFS rates, we recommend CMS raise the exemption threshold to 95% managed care participation and phase out the exemption entirely after two years. In many states some of the most clinically complex consumers remain in FFS programs and these may be the enrollees that most benefit from Payer-to-Payer APIs.

E. Prior Authorization Requirements, Documentation, and Decision API (§§ 431.80, 438.242)

Recommendation: We support the development of PARDD APIs that could streamline and automate the prior authorization process. Individuals are often harmed by delays or failures in prior authorization processes that require providers to file paperwork in the days or sometimes weeks after patient visits. Prior authorization processes are difficult and painful for families to navigate.<sup>28</sup> One survey of physicians found that over half (56%) reported that prior authorization "often" or "always" delays access to necessary care and more than one-third reported that prior authorization led to a serious adverse event, including hospitalizations, disability or even death.<sup>29</sup> If all information needed for prior authorization requests could be reviewed in real time, and in many cases possibly resolved in real time, it would allow providers and patients to consider next steps, treatment instructions, or other treatment options at the same visit. This would reduce burden and improve care. A majority of physicians report that they struggle to determine whether a particular service requires prior authorization.<sup>30</sup> Prior authorization processes, which are often manual, create extensive burdens for providers.<sup>31</sup>

We do not support the specific provisions allowing extensions for Medicaid and CHIP FFS programs. With respect to exemptions in states with low FFS rates, we recommend CMS

<sup>&</sup>lt;sup>28</sup> Carolyn Y. Johnson, "I wrote about high-priced drugs for years. Then my toddler needed one," Washington Post (Jan. 30, 2023), <a href="https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies">https://www.washingtonpost.com/wellness/2023/01/30/high-priced-drugs-step-insurance-policies</a>; David Armstrong, et al., "UnitedHealthcare Tried to Deny Coverage to a Chronically Ill Patient. He Fought Back, Exposing the Insurer's Inner Workings," ProPublica (Feb. 2, 2023), <a href="https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis.">https://www.propublica.org/article/unitedhealth-healthcare-insurance-denial-ulcerative-colitis.</a>

<sup>&</sup>lt;sup>29</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), https://www.ama-assn.org/system/files/prior-authorization-survey.pdf.

<sup>&</sup>lt;sup>30</sup> "Measuring progress in improving prior authorization," American Medicaid Association (2021 Update), <a href="https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf">https://www.ama-assn.org/system/files/prior-authorization-reform-progress-update.pdf</a>.

<sup>&</sup>lt;sup>31</sup> "2022 AMA Prior Authorization (PA) Physician Survey," American Medical Association (2023), <a href="https://www.ama-assn.org/system/files/prior-authorization-survey.pdf">https://www.ama-assn.org/system/files/prior-authorization-survey.pdf</a>; "Conducting Electronic Business Transactions: Why Greater Harmonization Across the Industry is Needed," 2019 CAQH Index (2020), <a href="https://www.cagh.org/sites/default/files/explorations/index/report/2019-cagh-index.pdf">https://www.cagh.org/sites/default/files/explorations/index/report/2019-cagh-index.pdf</a>.

raise the exemption threshold to 95% managed care participation and phase out the exemption entirely after two years. In many states some of the most clinically complex consumers remain in FFS programs and these may be the enrollees that most benefit from PARDD APIs.

## **Requests for Information**

# B. Request for Information: Electronic Exchange of Behavioral Health Information

We appreciate HHS's request for information on supporting electronic data exchange of behavioral health information between and among behavioral health providers, other healthcare providers, and patients, to inform care and treatment for individuals with behavioral health needs. Ensuring access to behavioral health care and coordination is particularly important for individuals covered by Medicaid and the Children's Health Insurance Program, who generally have higher rates of mental illness and substance use disorders. According to the Kaiser Family Foundation, over a third of individuals covered by Medicaid have a mental illness and/or substance use disorder.<sup>32</sup> In addition, according to CMS,<sup>33</sup> over 30 percent of non-institutionalized children ages three to 17 covered by Medicaid and CHIP had a mental, emotional, development, or behavioral problem in 2020 with national pediatric provider groups declaring a national emergency in child and adolescent mental health in fall of 2021 that remains ongoing.<sup>34</sup>

Multiple approaches will be needed to address the longstanding crisis in children's mental health. Ensuring appropriate care integration, including through the use of health information technology, can be leveraged as a tool in the toolbox to better support individuals with behavioral health needs. Yet, according to the Commonwealth Fund, provider practices with higher shares of Medicaid patients were less likely to fully adopt electronic health record systems with fewer than two-thirds of practices with a high concentration of Medicaid patients having fully adopted electronic health record systems by 2014-2019.<sup>35</sup> In addition, as noted by HHS in this proposed rule and by the Medicaid and CHIP Payment and Access Commission, behavioral health providers have also

<sup>&</sup>lt;sup>32</sup> Heather Saunders, et al., "Demographics and Health Insurance Coverage of Nonelderly Adults With Mental Illness and Substance Use Disorders in 2020," Kaiser Family Foundation (June 2022), <a href="https://www.kff.org/medicaid/issue-brief/demographics-and-health-insurance-coverage-of-nonelderly-adults-with-mental-illness-and-substance-use-disorders-in-2020">https://www.kff.org/medicaid/issue-brief/demographics-and-health-insurance-coverage-of-nonelderly-adults-with-mental-illness-and-substance-use-disorders-in-2020</a>.

<sup>&</sup>lt;sup>33</sup> Centers for Medicare and Medicaid Services, "2022 Medicaid and CHIP Beneficiary Profile: Enrollment, Expenditures, Characteristics, Health Status, and Experience," <a href="https://www.medicaid.gov/medicaid/quality-of-care/downloads/beneficiary-profile-2022.pdf">https://www.medicaid.gov/medicaid/quality-of-care/downloads/beneficiary-profile-2022.pdf</a>.

<sup>&</sup>lt;sup>34</sup> American Academy of Pediatrics, "AAP-AACAP-CHA Declaration of a National Emergency in Child and Adolescent Mental Health, (Oct. 19, 2021)," <a href="https://www.aap.org/en/advocacy/child-and-adolescent-healthy-mental-development/aap-aacap-cha-declaration-of-a-national-emergency-in-child-and-adolescent-mental-health">https://www.aap.org/en/advocacy/child-and-adolescent-healthy-mental-development/aap-aacap-cha-declaration-of-a-national-emergency-in-child-and-adolescent-mental-health</a>.

<sup>&</sup>lt;sup>35</sup> Dong Ding, "Are Medicaid Patients Seen in Office-Based Practices Getting High-Quality Primary Care?," Commonwealth Fund (Jan. 2023), <a href="https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/medicaid-patients-office-practices-high-quality-primary-care">https://www.commonwealthfund.org/publications/issue-briefs/2023/jan/medicaid-patients-office-practices-high-quality-primary-care</a>.

generally adopted information technology at lower rates compared with other providers.<sup>36</sup> As the primary payer of behavioral health care in the United States and now providing health coverage to over half of the nation's children, ensuring Medicaid has the tools and resources it needs to meet the health needs of the millions of Americans and children who depend on the program is critically important.

Accordingly, we support efforts to advance behavioral health care delivery and coordination by better supporting behavioral health providers in their ability to electronically share health information across providers and with patients while maintaining appropriate patient privacy protections (including those relevant to the specific privacy needs of pediatric and other vulnerable populations). We also encourage HHS to issue guidance on how states can use Medicaid authorities and other federal resources to promote behavioral health integration including as it relates to pediatric populations and providers and through the use of health information technology.

# D. Request for Information: Advancing Interoperability and Improving Prior Authorization Processes for Maternal Health

See comment above, at page 13.

#### **Conclusion**

Thank you again for the opportunity to make the above comments in support of the proposed rule. Please contact Leo Cuello (Leo.Cuello@georgetown.edu) if you have any questions.

Respectfully submitted,

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<sup>&</sup>lt;sup>36</sup> Medicaid and CHIP Payment and Access Commission, "Report to Congress on Medicaid and CHIP; Chapter 4, Encouraging Health Information Technology Adoption in Behavioral Health: Recommendations for Action" (June 2022), <a href="https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-4-Encouraging-Health-Information-Technology-Adoption-in-Behavioral-Health.pdf">https://www.macpac.gov/wp-content/uploads/2022/06/Chapter-4-Encouraging-Health-Information-Technology-Adoption-in-Behavioral-Health.pdf</a>.