September 9, 2024

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244–1850

Submitted electronically via regulations.gov

Re CMS-1809-P: Medicare and Medicaid Programs: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, Including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information; Medicaid and CHIP Continuous Eligibility; Medicaid Clinic Services Four Walls Exceptions; Individuals Currently or Formerly in Custody of Penal Authorities; Revision to Medicare Special Enrollment Period for Formerly Incarcerated Individuals; and All-Inclusive Rate Add-On Payment for High-Cost Drugs Provided by Indian Health Service and Tribal Facilities

Dear Administrator Brooks-LaSure:

On behalf of Families USA and our undersigned partners, thank you for the opportunity to comment on the Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; Quality Reporting Programs, including the Hospital Inpatient Quality Reporting Program; Health and Safety Standards for Obstetrical Services in Hospitals and Critical Access Hospitals; Prior Authorization; Requests for Information for Calendar Year 2025 (herein after "Proposed Rule").

All families and individuals in the United States should have access to high-quality, affordable, equitable health coverage and improved health. This Proposed Rule expands access to Medicare coverage for eligible individuals who are involved in the criminal justice system, and it expands Medicaid coverage for children, American Indians and Alaskan Natives, people with behavioral health needs, and rural communities. With 82 million of our nation's children and families covered by Medicaid and CHIP, and nearly 10,000 formerly incarcerated people eligible for Medicare, CMS's work to expand care and coverage for these populations is a promising step toward step toward increasing and maintaining health care access for all Americans.[iii] Importantly, by focusing on historically marginalized communities, the Proposed Rule also promotes health equity and helps to reduce health care disparities.

We strongly support policies in the Proposed Rule that would expand access to coverage and payment for critical services through Medicare, the Children's Health Insurance Program (CHIP), and Medicaid. **We recommend that CMS and HHS work swiftly to finalize the following provisions and take additional steps outlined below to expand coverage and care to ensure historically marginalized communities can achieve their best health.**

Our comments are focused on the following sections of the proposed rule:

- XX. Provisions Related to Medicaid and the Children's Health Insurance Program

- XVIII. Medicaid Clinic Services Four Walls Exceptions
- XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

XX. Provisions Related to Medicaid and the Children's Health Insurance Program

We strongly support CMS proposals that codify policies in the Consolidated Appropriations Act (CAA) of 2023 that require states to provide 12 months of continuous Medicaid and CHIP eligibility to children under the age of 19 and prevent states from disenrolling children from CHIP for failure to pay premiums during a continuous eligibility period.

The CAA of 2023 requires states to provide 12 months of continuous coverage for children who meet their state's Medicaid and CHIP eligibility requirements. CMS issued guidance to implement this requirement in a September 2023 letter to state health officials that outlined the populations covered, exceptions to the requirement, and timelines for Medicaid and CHIP continuous coverage.[iii] Additionally, CMS acknowledged, but did not provide guidance on the state option under CHIP to disenroll children for failure to pay premiums or enrollment fees, which the CAA did not address.

Proposed Rule

In the Proposed Rule, CMS aligns Medicaid and CHIP regulations with the CAA's continuous eligibility requirements to further codify the requirement that states provide continuous eligibility to children for 12 months and up to the age of 19. Additionally, the Proposed Rule amends existing CHIP regulation by removing the option for states to disenroll children from CHIP for failure to pay premiums or enrollment fees during a continuous eligibility period.[iv] The Proposed Rule, if finalized, would protect children and low-income families from harmful coverage terminations.

Background on Continuous Medicaid and CHIP Coverage

Medicaid and CHIP are the primary sources of coverage for nearly half of all children in the country – and disproportionately for children of color – and are vital to children's access to health care.[v,vi] For low-income children who have higher rates of asthma, obesity, and mental health conditions, Medicaid and CHIP coverage means they are able to seek routine and specialty medical care without financial burden on their families due to high health care costs.[vii] Continuous eligibility, which guarantees ongoing health care coverage for enrollees, helps ensure that children stay enrolled in health coverage and have access to important health care services, regardless of temporary fluctuations in eligibility. During the COVID-19 public health emergency, the Families First Coronavirus Response Act implemented a continuous coverage policy in Medicaid which helped lead to significant declines in the rate of uninsured children.[viii,ix] When Congress ended the continuous coverage requirement on March 31, 2023, states moved to redetermine children's Medicaid and CHIP eligibility.[x] Without continuous coverage protections in place, over 24 million children were disenrolled from Medicaid and CHIP, many for procedural reasons such as out-of-date contact information or incomplete renewal forms, rather than ineligibility.[xi]

The end of the COVID-19 continuous coverage protections impacted low-income children's access to health care across the country. Data from several states found that fewer children were enrolled in Medicaid and CHIP coverage after this redetermination period than before the pandemic, signaling a drop in enrollment of eligible children.[xii] In Florida, where nearly 600,000 children were disenrolled from

health care coverage, the state filed a lawsuit arguing that CMS overstepped its authority by preventing states from disenrolling children from CHIP for non-payment of premiums.[xiii] Although the lawsuit was dismissed by the federal judge for lack of standing, it shows what lengths some states will go to avoid providing necessary care and coverage for low-income children.[xiv]

Continuous coverage allows families to get the care they need to improve and maintain their children's health without fear of disenrollment due to changes in circumstance or inability to pay premiums. Without access to health coverage, children are less likely to get routine medical care or treatment for injuries, and when they do access care their families are more likely to fall into debt due to increasingly high and unexpected medical costs.[xv] Codifying the CAA's Medicaid and CHIP continuous coverage for children and amending CHIP regulation to prevent states from disenrolling children for failure to pay enrollment fees or premiums will ensure that children can maintain health care coverage and receive necessary care.

XVIII. Medicaid Clinic Services Four Walls Exception

We strongly support CMS's proposals to amend the Medicaid clinic services regulation to authorize federal reimbursement for services that the Indian Health Service (IHS) and tribal clinics furnish outside the "four walls" of a freestanding clinic, and the optional state exception to the "four walls" requirement for behavioral health clinics and clinics in rural areas.

Proposed Rule

The Proposed Rule modifies the "four walls" requirement for Medicaid clinic services by creating:

1. a permanent, mandatory exception for Indian Health Service (IHS) and tribal clinics;
2. optional state exceptions to clinics primarily organized to treat outpatient behavioral health disorders; and
3. an optional state exception for clinics located in rural areas.

If finalized, this proposed rule would improve patient access to care by allowing payment to more providers that offer services outside of a clinic setting.

Background on Medicaid Coverage of Clinic Services

Clinic services are an optional state benefit for states and are currently reimbursed using an encounter visit rate, physician fee schedule rate or reconciled costs.[xvi] Services must meet requirements outlined in 42 CFR 440.90 for Medicaid reimbursement and include two types of services: one, furnished inside a clinic of "four walls" of the facility by a physician or dentist and the other, furnished outside a clinic. Under the existing four walls requirement, either the physician or patient is required to be on site when services are provided, unless the services are provided to an individual who does not reside in a permanent dwelling or does not have a fixed home or mailing address.[xvii] While this policy ensures that care is tied to a clinic's facility infrastructure, in some cases it can limit flexibility in service delivery and the ability to account for the diverse needs of patients who may benefit from alternative service delivery options.

The current "four walls" exception for unhoused individuals, which allows individuals facing chronic homelessness to receive care in community-based settings, illustrates the recognition of the need for flexibility in situations where patients face significant barriers to accessing fixed-location care and where providers need reimbursement for delivering these services.[xviii] Expanding these exceptions enhances access to outpatient care, supports high-needs populations, and reimburses clinic providers where the traditional clinic model does not adequately meet the needs of the community. In addition, allowing higher reimbursement rates for these services can help redistribute providers in key areas with unmet needs, thereby expanding access to care.

Amending the "Four Walls" Requirement for IHS and Tribal Clinics, Behavioral Health, and Clinics in Rural Areas

Expanding access to care for IHS and tribal clinics, behavioral health clinics, and clinics in rural areas is essential for addressing critical healthcare needs and overcoming persistent systemic barriers that impact disinvested American Indian and Alaskan Native (AI/AN) and rural communities.

Indian Health Service (IHS) and Tribal Clinics

The current four-walls requirement poses challenges for Indian Health Service (IHS) and tribal clinics. These clinics often provide services outside their physical locations to better serve their communities. For example, Indian health providers often set up mobile units and triage centers to better meet their communities' needs.[xix] Reimbursement policy that fails to pay for these services can inhibit access to care for American Indians and Alaska Natives.[xx] When these clinics do find a way to offer services outside of the clinic, they often have complicated billing processes that affect the financial sustainability of these programs.

Amending the "four walls" requirement to provide an exception for IHS and tribal clinics is crucial for these providers and the communities they serve.[xxi,xxii,xxiii] Chronic underinvestment in American Indian and Alaska Native communities has resulted in poor health outcomes, such as high rates of liver disease, kidney disease, and cancer.[xxiv,xxv] CMS has made significant strides to improve American Indian and Alaska Native health over the course of the Biden-Harris Administration, including publishing the Framework for Advancing Health Care in Rural, Tribal, and Geographically Isolated Communities; advancing payment models such as AHEAD that improve rural access to care; and strengthening partnerships with rural and tribal stakeholders committed to improving care and access.[xxvi]

However, more investment is needed to improve the health outcomes of the AI/AN community. The "four walls" exception for IHS hospitals and tribal clinics under this Proposed Rule will increase community-based care in tribal communities; better allow for care to be delivered to AI/AN seniors in their homes; and facilitate improved access to health care and health-related social services for AI/AN individuals.[xxvii,xxviii]

Behavioral Health Clinics

The U.S. faces a severe crisis in access to mental health care, marked by high costs, long wait times, and a lack of sufficient providers.[xxix] In 2020, among those with serious mental health illnesses, almost half reported not receiving treatment when it was needed.[xxx] Rates of unmet needs are even higher for

Medicaid beneficiaries, where 1 in 3 have a mental illness and 1 in 5 struggle with substance use disorders.[xxxi] Moreover, demand for services has surged since the pandemic. Alcohol and opioid overdose deaths rose by 31% and 63%, respectively, and anxiety and depression rates have increased by 25%.[xxxii,xxxiii] Medicaid plays a crucial role in addressing these disparities by providing essential funding and coverage as the largest payer for behavioral health services.[xxxiv]

The Proposed Rule's exception to the "four walls" requirement for behavioral health services has the potential to lower barriers to mental health treatment and expand access to care for Medicaid beneficiaries. Nearly 74% of people in the U.S. live in a mental health provider shortage area and are not getting their mental health needs met.[xxxv] Other barriers such as stigma, cost, and lack of education make mental and behavioral health care difficult or impossible to reach for many patients who need this care.[xxxvi] The Proposed Rule resolves a critical barrier to accessing mental health care by permitting reimbursement for behavioral health care provided outside of a clinic, through channels such as mobile crisis units, telehealth, and community-based settings, where care can be delivered to people where they are, without additional challenges posed by high costs, long travel, or long wait times.

Rural Clinics

The Proposed Rule also extends the "four walls" exception to clinics in rural areas, granting providers the flexibility to be reimbursed by Medicaid for clinical services provided outside the clinic. In doing so, the "four walls" exception helps bridge gaps in care, reduces health disparities, and enhances access to timely treatment and preventive services for rural communities.

Rural clinics face geographical constraints that make it difficult to adhere strictly to the four walls requirement.[xxxvii] Only 10% of primary care practitioners provide care in rural communities, and even fewer specialty care providers serve rural areas.[xxxviii] This provider shortage means patients must travel long distances to receive care, and without reliable transportation patients are forced to delay or forgo essential care.[xxxix] These barriers to health care access contribute to severe health disparities between rural and urban areas.[xl] Rural residents experience higher rates of death from heart disease, cancer, and stroke, underscoring the critical need for more accessible prevention and treatment services.[xli]

Furthermore, the Proposed Rule can play an outsized role in narrowing disparities in maternal health outcomes, especially critical given the persistent and devastating maternal health crisis in America. Reimbursing care delivered outside of the clinic, such as through telehealth and community-based services, is crucial for enhancing maternal health outcomes in rural areas, where maternal mortality rates are significantly higher.[xlii] Since 2010, over 130 rural hospitals have closed with severe consequences on maternal health care access. This decline has worsened maternal health outcomes with increased rates of preterm births, reduced prenatal care, and higher maternal mortality.[xliii,xliv,xlv,xlvi] The Proposed Rule gives maternal health care providers the flexibility to provide care in the community or through telehealth, ensuring that pregnant people living in rural communities have access to vital pre- and postnatal care without barriers posed by excessive travel, maternity ward closures, or cost.[xlvii]

In rural communities, where patients face barriers to care due to high costs, poorer maternal health outcomes, long travel distances, hospital closures, and provider shortages, flexibility to provide care outside of clinics is essential to meeting the health needs of residents. If finalized, the Proposed Rule

would allow Medicaid beneficiaries in rural communities to receive care in their communities and homes and providers to be reimbursed for that care, addressing many long-standing barriers to care access and helping reduce health disparities in rural America.

XXIII. Individuals Currently or Formerly in the Custody of Penal Authorities

We strongly support CMS's proposal to narrow the Medicare definition of in "custody" so that it no longer includes people who are under supervised release or required to live under home detention. This change would allow Medicare to pay for important health care services for Medicare-eligible, formerly incarcerated individuals. We also support the proposal to provide a special enrollment period that enables formerly incarcerated individuals to enroll in Medicare Part A and/or Part B and receive Medicare-covered care soon after they leave incarceration.

Medicare Coverage and Payment for Services for People in "Custody"

Under current Medicare law, the federal government is prohibited from paying for care for people considered "in the custody of penal authorities." Medicare rules define "custody" broadly to include some formerly incarcerated individuals, including people in home detention, on parole, or on probation.[xlviii] The Proposed Rule would narrow the definition of "custody" to allow formerly incarcerated individuals in home detention, on probation, or parole to enroll in Medicare and use their Medicare coverage to pay for health care. This proposed change, if finalized, would mark a significant step to address long-standing systemic barriers preventing access to care for justice-involved individuals, and would advance racial justice and health equity in the U.S. health care system.

Individuals on parole, probation, or in home detention have historically been ineligible for Medicare coverage, leaving this population of older Americans and people with disabilities with limited or no access to health care.[xlix] This lack of access to basic health care coverage is compounded by the fact that incarcerated individuals – a disproportionate number of whom are Black and Hispanic – face significant barriers reintegrating into their community after incarceration, including difficulties finding and maintaining employment, safe housing, and healthy relationships.[l,li,lii] On top of this, people leaving incarceration often deal with chronic physical and mental health conditions.[liii,liv,lv] Incarcerated people are 10 times more likely to have hepatitis C, six times more likely to have tuberculosis, and three times more likely to have HIV than those who are not incarcerated.[lvi] Additionally, formerly incarcerated people with substance use disorder have a 10 times greater risk of opioid overdose than the general population if they return to regular usage without access to treatment.[lvii] As people leave incarceration, health care coverage is essential so that care can be accessed as soon as they transition back into their communities, to avoid negative health outcomes.

Ensuring that formerly incarcerated people are able to qualify for Medicare coverage will also result in significant cost savings for states and health systems.[lviii] Formerly incarcerated people are at higher risk of emergency department visits and hospitalization and are less able to pay for care than those without a criminal justice history.[lix] The reliance of emergency department and hospital care for this population results in over $5 billion in health care spending annually, most of which is attributed to uncompensated care costs.[lx] Expanding Medicare eligibility to formerly incarcerated individuals ensures that they can access routine, preventive care and reduces unnecessary uncompensated care costs that states and

hospitals may otherwise incur from treating a high-risk, uninsured formerly incarcerated population through the delivery of fragmented and inefficient care.[lxi]

Special Enrollment Periods for Formerly Incarcerated Individuals

The Proposed Rule's adoption of the new definition of "custody" also allows formerly incarcerated individuals reentering the community to have access to a special enrollment period for Medicare that aligns with their release to ensure they can access care in a timely manner. The Proposed Rule streamlines the process for enrolling in Medicare by requiring the Social Security Administration (SSA) to determine whether an individual is eligible to enroll in Medicare under a special enrollment period based on the reestablishment of their old age, survivors, and disability insurance (OASDI).[lxii]

Under current federal law, formerly incarcerated individuals can qualify for a Medicare special enrollment period by demonstrating they are eligible for Medicare coverage by providing a record of their release through discharge documents, and proving that they missed their enrollment period due to incarceration.[lxiii] This places all of the responsibility for determining eligibility on the formerly incarcerated individual during a time when they are facing other challenges associated with reintegrating into their communities, resulting in unnecessary stress and delays in care for individuals who cannot retrieve and submit the required paperwork in a timely manner. Conversely, the SSA automatically redetermines a person's OASDI benefits, which are suspended for incarcerated individuals, using data reported from penal institutions and correctional facilities to confirm that a beneficiary is no longer incarcerated.[lxiv,lxv] The Proposed Rule eliminates the process that forces formerly incarcerated individuals to self-establish their eligibility for a Medicare special enrollment period and instead would allow SSA to establish a formerly incarcerated individual's eligibility automatically in line with how OASDI benefits are determined. This will alleviate additional burden and delays in care and coverage for individuals who are already facing multiple barriers reintegrating into their communities.

We commend CMS for moving in this direction and further recommend that CMS explore options to enable individuals leaving incarceration to pre-enroll in Medicare coverage prior to their release, similar to an option available under a Medicaid 1115 waiver, to avoid lapses in coverage and care.

Under federal Medicaid rules, CMS permits states to use 1115 waivers to pre-enroll inmates into Medicaid up to 90 days prior to their release, even though the Medicaid Inmate Exclusion policy terminates or suspends an individual's Medicaid eligibility while incarcerated.[lxvi] Allowing states to pre-enroll inmates into Medicaid *before* their release date directly increases immediate access to health care services for this population upon reentry into their communities, and is associated with significant increases in health care utilization.[lxvii] More direct enrollment approaches can ensure that formerly incarcerated people have access to the care they need when they are the most at risk of an adverse health outcome.[lxviii] Studies have found that death by opioid overdose is most likely to happen in the two weeks following a person's release from incarceration.[lxix] This approach to improve pre-enrollment in Medicaid for inmates offers a compelling model that could potentially be modified for the Medicare program to streamline enrollment processes and ensure formerly incarcerated individuals have access to critical health care services upon release from prison.

Conclusion

The changes that HHS and CMS advance in this Proposed Rule would significantly improve access to health coverage and care for justice-involved people, American Indians and Alaska Natives, and children from low-income families and their communities. The undersigned organizations strongly commend CMS's commitment to health equity and applaud the improvements the Biden-Harris Administration has made in health access and outcomes for these and other historically marginalized communities. We believe that to achieve meaningful health equity, we must continue to improve access to care and coverage for the communities that have the highest needs and suffer from the largest health care disparities.

We look forward to continuing to work with you to develop strategies to ensure that those disproportionately burdened by poor health outcomes and historic disinvestment can obtain the high-quality health care and support services they need to flourish.

For questions or comments regarding the recommendations made in this letter, please reach out to Christine Nguyen, Manager of Health Equity Strategies at Families USA at cnguyen@familiesusa.org. Thank you for your time and consideration.

Sincerely,

Families USA
AgeOptions
Allergy & Asthma Network
Autistic Women & Nonbinary Network
Clear Healthcare Advocacy
Colorado Consumer Health Initiative
Consumers for Affordable Health Care
Democratic Disability Caucus of Florida
Epilepsy Foundation
Health Care Voices
Iowa Citizen Action Network
National Association of Social Workers
National Center for Medical-Legal Partnership
National Disability Rights Network (NDRN)
Pennsylvania Health Access Network
Primary Care Development Corporation
Rebuilding Independence My Style
Tennessee Health Care Campaign
The Children's Partnership
The Coalition for Hemophilia B

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