

#### VIA ELECTRONIC TRANSMISSION

June 30, 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: Medicaid Program; Ensuring Access to Medicaid Services; Proposed Rule - CMS-2442-P

Dear Secretary Becerra,

Thank you for the opportunity to comment on, "Medicaid Program; Ensuring Access to Medicaid Services; Proposed Rule - CMS-2442-P," hereinafter referred to as the "proposed access 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.

We are generally supportive of the provisions in the proposed access rule, though we detail some recommendations for improvement below. We believe the proposed changes to the Medicaid Advisory Committee and Beneficiary Advisory Group will significantly improve the ability of people with lived experiences to contribute meaningfully to Medicaid policy and operations. With respect to access to care and Medicaid payment rates, we believe the new emphasis on transparency will enable a broad Medicaid stakeholder community to hold states and CMS accountable for compliance with critical access requirements laid out in the Medicaid statute. However, we believe CMS should work towards more alignment between Medicaid and Medicare rates, rather than continuing to allow substandard payment rates in Medicaid. Finally, we believe the proposed changes to home and community-based services will improve access to and quality of critical services for children with special health care needs and people with disabilities.

#### I. Medicaid Advisory Committee and Beneficiary Advisory Group

The proposed access rule makes important changes to the current Medical Care Advisory Committee (MCAC) structure in Medicaid. MCACs are stakeholder committees that every state must establish to provide feedback and recommendations to the state Medicaid agency. The current MCAC regulations do not include sufficient standards to ensure meaningful participation by Medicaid beneficiaries, effective MCAC function, and transparency in MCAC processes. The proposed access rule includes numerous provisions to address these and other long-standing limitations with the MCAC process, and has the potential to transform the operation of state Medicaid programs, making them more attuned and responsive to the lived experiences of enrollees. Our comments broadly support CMS's proposed changes and additions and make some recommendations to improve the proposed rule.

<u>Recommendation</u>: Finalize the proposed access rule provisions on MAC and BAG with the addition of our recommendations below.

a. New dual advisory committee structure

Under current regulations, every state is required to operate a singular MCAC, that convenes various Medicaid stakeholders, including beneficiaries, to provide recommendations to the state agency. The proposed access rule would change the MCAC name to Medicaid Advisory Committee (MAC). It would also create a new Beneficiary Advisory Group (BAG), comprised entirely of individuals with lived experience in Medicaid (including beneficiaries, family members, or caregivers), that will provide direct feedback to the state Medicaid agency *and* participate in the MAC. Our comments strongly support this proposal.

We strongly support the creation of a BAG in addition to the MAC. While we believe it is very important for the states to continue to operate MACs to get a broad range of feedback about Medicaid function, the BAG will be critical to ensuring meaningful input from Medicaid beneficiaries. While current regulations do require Medicaid beneficiary participation on MACs, Medicaid beneficiaries often struggle to participate on a committee where they are outnumbered by high-powered industry leaders, such as managed care or hospital executives. Providing a safe and dedicated space for Medicaid beneficiaries (potentially including family members or caregivers) to discuss the issues they face, ask questions, and offer advice directly to state leadership would dramatically improve the depth and quality of Medicaid beneficiary participation. This in turn will lead to state Medicaid programs that are better informed and more responsive to the problems beneficiaries face.

<u>Recommendations</u>: We strongly recommend that CMS finalize the proposed dual advisory committee structure.

b. MAC Composition

Current regulations provide some minimal requirements for MAC composition, but insufficient detail to ensure robust participation by Medicaid beneficiaries and other stakeholders. The proposed access rule would set more detailed standards. First and foremost, it would require that at least 25 percent of the MAC committee be drawn from the BAG membership (i.e., Medicaid beneficiaries). Second, the proposed access rule would require that MACs include at least one stakeholder from each of several categories, including a Medicaid beneficiary advocacy organization category, clinical providers, and Medicaid managed care plans. It also requires participation from at least one other state agency that serves Medicaid enrollees (such as a foster care agency), in an ex-officio role. Our comments support these proposals.

We strongly support setting a fixed standard for MAC participation of 25 percent of the membership coming from the BAG. We recommend that CMS not reduce the 25 percent threshold. Including a specific threshold is important to ensure there is a clear minimum standard for consumer participation.

We also support the proposed access rule including more detail about other stakeholder composition requirements. In particular, we support the inclusion of a beneficiary advocacy organization at (d)(2)(A), both because such organizations may understand and represent beneficiary problems from a unique perspective and because beneficiary MAC members may feel more support with an advocacy organization on the MAC. We also support the inclusion of one (or more) other state agencies that serve Medicaid enrollees in an ex-officio role, as this may help advance the coordination of state Medicaid programs and related social services, such as nutrition, child welfare or housing supports.

While we support the general categories for MAC membership set out in the proposed access rule, we think the rule should provide more details about provider inclusion. Specifically, to ensure the Medicaid agency is focused on health and prevention broadly, we recommend that at least one primary care provider be required as a member. Additionally, because children constitute 53 percent of Medicaid/CHIP enrollment and approximately half of the children in the country are insured by Medicaid,<sup>1</sup> we believe there should also be at least one pediatrician. CMS could consider additionally requiring one provider for maternity care and one for behavioral health, which have been put forward as regulatory priorities.

<u>Recommendations</u>: We recommend that CMS finalize the proposed MAC composition provisions, including preserving (at least) a 25 percent threshold for Medicaid beneficiary membership. We further recommend that CMS require the MAC to include at least one primary care provider and one pediatrician.

c. BAG design and function

The proposed access rule requires that the newly created BAG be comprised of "[i]ndividuals who are currently or have been Medicaid beneficiaries and individuals with direct experience supporting Medicaid beneficiaries (family members or caregivers of those enrolled in Medicaid)." The rule further requires that the state convene BAG meetings

<sup>&</sup>lt;sup>1</sup>Conmy, A et. al., "Children's Health Coverage Trends" ASPE (March 2, 2023),

https://aspe.hhs.gov/sites/default/files/documents/77d7cc41648a371e0b5128f0dec2470e/aspe-childrenshealth-coverage.pdf and CMS, Medicaid & CHIP Scorecard (April 2021), https://www.medicaid.gov/stateoverviews/scorecard/who-enrolls-medicaid-chip/index.html.

in advance of MAC meetings. At least one member of the state agency executive staff must be present at the BAG meetings. Our comments support these policies, with some additions.

We support the membership of the BAG including Medicaid beneficiaries as well as family and caregivers of beneficiaries. It is important to include family and caregivers as some Medicaid enrollees, including children, may be unable to represent themselves on the BAG (and MAC). We recommend that CMS consider improving the proposed rule by requiring states to include beneficiaries representing a cross-section of the Medicaid program, including, at a minimum, beneficiaries from major categorical groups (children, pregnant people, parents and other adults, people with disabilities, and seniors), as well as an appropriate balance of urban and rural enrollees and enrollees in different major delivery systems. In some states, some types of enrollees may be harder to find, and without requirements in place states may consistently underrepresent those types of enrollees. We also suggest that CMS allow BAG members to have an unlimited number of terms. Longserving BAG members can build expertise that will benefit the state agency and new BAG members alike.

We support the requirement for the BAG to meet before every MAC meeting – this will allow the BAG members who participate on the MAC an opportunity to prepare and will ensure the BAG is keeping up with the information the MAC is receiving and the issues the MAC is considering. In Pennsylvania, the consumer subcommittee meets the day before the MAC meeting, which minimizes travel and ensures timely discussion of the relevant issues. We also support the requirement for one member of the state agency executive staff to participate in BAG meetings. It is critical for an accountable state Medicaid leader to meet with the BAG and be available to provide updates, answer questions, and receive recommendations.

<u>Recommendations</u>: We recommend that CMS finalize the BAG design proposal, but add provisions to require BAG membership to include beneficiaries representing a cross-section of the Medicaid program, including, at a minimum, beneficiaries from major categorical groups (children, pregnant people, parents and other adults, people with disabilities, and seniors), as well as an appropriate balance of urban and rural enrollees, with an unlimited number of terms. CMS should also encourage the BAG meeting to be just before the MAC meeting to minimize travel and ensure timely discussion of relevant issues.

#### d. Transparency

The current regulations include no provisions around transparency of MCACs. The proposed access regulation would add numerous transparency requirements. The state must develop and publish: processes to recruit and appoint committee members, bylaws for committee governance, committee member lists, the meeting schedule, and past meeting minutes and attendee lists. The state would be required to convene the MAC at least quarterly (and additionally as needed) and at least two of these meetings must be open to the public and offer the public a chance to speak. The BAG can make meetings public at the choice of the BAG members. Our comments support these proposals, with some changes.

We support the requirements for states to develop and publish MAC processes. The current lack of guidance on MAC processes leads to confusion in states and inconsistency across states. It can also lead to real or perceived unfairness in processes (such as appointment to the MAC), which can erode the MAC's credibility. Most importantly, clear processes that are publicly posted will lead to more engagement in the MAC by beneficiaries and other stakeholders, which will improve the advice the state agency receives.

We also support the requirement for (at least) quarterly MAC meetings, though we recommend that all MAC meetings should be open to the public. We support retaining the flexibility for the BAG to make its meetings public at the BAG's choice, as it may be necessary for beneficiaries to have a private forum for difficult conversations, and beneficiaries may be private individuals who do not wish to have public exposure.

# <u>Recommendations</u>: We recommend CMS finalize the proposed provisions related to transparency, except that CMS require that all MAC meetings be open to the public.

e. State support for MAC and BAG

Current CMS regulations require state agencies to assist the MAC so that it can make recommendations and to provide necessary financial support to beneficiaries. The proposed access rule builds upon these supports. The proposed regulation adds requirements for states to support the recruitment of members, planning of meetings, producing meeting minutes and state response lists, and to provide information and research. The prosed access rule preserves, but does not change, the requirement to provide necessary financial support to beneficiaries. Our comments support these proposals, with some revisions.

We support the expanded obligations for states to support MAC and BAG participation in the proposed access rule. State support for MAC and BAG processes and policy development is critical to the bodies being able to achieve their mission. It is particularly helpful to require the state to develop and publish meeting minutes and state action lists, to ensure there is accountability and follow up for MAC and BAG recommendations.

However, we do not believe the proposed access regulation goes far enough in supporting BAG members. BAG members, who are ordinary state residents with <u>no health policy</u> training, may be asked to comment on a range of complex topics from prescription drug rebates to behavioral health carveouts to section 1115 demonstration budget neutrality calculations. To do this meaningfully, they need health policy support – specifically, policy support that is <u>independent</u> of the state (which has a conflict of interest in asking beneficiaries for feedback on its own proposals). CMS should require states to allow BAGs to retain at least one counsel or policy expert advisory organization, authorized to attend BAG meetings and represent the BAG (at the BAG's will). CMS could require states to provide the BAG with the names of at least three potential support organizations, and allow the BAG to select one, or another organization of its own choice, or none if it so chooses, to be a BAG support organization. We note that one of the organizations that could be offered

to the BAG as a support option would be the MAC (d)(2)(A) beneficiary advocacy organization. Finally, we believe that CMS should require states to reimburse (or provide the BAG a budget to reimburse) the BAG support organization. The purpose of the reimbursement would not be to defray all costs related to supporting the BAG, but rather to provide an honorarium to support organizations.

We also support the requirement to provide financial assistance to beneficiaries, but do not believe the regulation goes far enough. First, beneficiaries should not have to establish "need" for basic financial assistance with attending the meeting – including transportation, meals, lodging, and health and attendant care expenses. Medicaid enrollees are by definition lower income and any expenses that must be borne by the beneficiary are a barrier to participation in the BAG and MAC. Second, CMS should require states to compensate BAG members for their participation time (unless the BAG member declines). BAG and MAC members may need to take time off work, which is often unpaid, to participate. We note that most other members of the MAC likely participate during work hours as part of their work responsibilities – for which they are paid – and likely also receive reimbursement from their employers for travel and lodging to meetings. Third, we believe that a BAG member's reimbursement and compensation should not impact their Medicaid eligibility. So, CMS would need to create a mandatory exception to ensure that income related to BAG service would not put a participant over a program income limit.

<u>Recommendations</u>: We recommend that CMS finalize provisions supporting the MAC and BAG, with several additions. We recommend that CMS establish a requirement for states to allow and reimburse a BAG health policy support counsel or organization, independent of the state, and selected and serving at the BAG's will. We recommend that the state be required to identify for the BAG three potential such organizations for the BAG, one of which could be the (d)(2)(A) beneficiary advocacy organization. The BAG would retain ultimate choice and control over the support organization and the terms of its service or representation. We recommend further that reimbursement for beneficiary participation costs in the BAG and MAC be mandatory (not tied to need) and that CMS require compensation for BAG members for BAG and MAC participation unless the enrollee declines compensation. We also recommend that CMS create an exception to Medicaid income counting for BAG reimbursement and compensation.

f. Accessibility and Participation

Current regulations require that MAC members have the opportunity for participation and agency assistance to enable effective recommendations, but no specific provisions ensuring accessibility of MAC meetings. The proposed access rule requires states to take reasonable steps to make MAC and BAG meetings accessible to people with disabilities and limited English proficiency, including allowing participation virtually or by phone. It also requires states to select meeting times and locations to maximize attendance. We support all of the provisions supporting accessibility and participation for MAC and BAG processes.

<u>Recommendation</u>: We recommend CMS finalize the proposed accessibility and participation provisions.

### g. Role of the MAC and BAG

Current regulations only require states to rely on the MAC for advice on "health and medical care services," which could be construed narrowly to only allow input on *service* issues. The proposed access rule would expand the role of the MAC and BAG to provide recommendations on all elements of state Medicaid programs, including services, eligibility and enrollment processes, communications, and quality of care, among other policy development topics. Finally, the proposed access rule also requires the state to support the MAC in the development of an annual report discussing MAC activities and recommendations, including a summary of BAG recommendations and state follow-up. Our comments support this expansion, with some suggested additions.

We support the broader mission for the MAC and BAG set out in the proposed access rule. In fact, we believe almost all current MACs provide input on a wide range of issues, so this change should be minimally disruptive while clarifying the role of the MAC and ensuring it is not diminished. We also support the new requirement for a MAC and BAG annual report, which should build accountability into the process.

However, we recommend that CMS make four additions to the regulation. First, § 431.12(g) is missing a critical reference to "access to services," and this should be added. Second, we believe the MAC and BAG can only be truly effective if they are part of the development of state Medicaid policy and administration. This means states should be consulting with the MAC and BAG <u>prior</u> to making decisions; we are aware of situations where states may use the current MCAC only to provide informational updates about decisions that have already been made. We recommend that CMS's regulatory text clarify that states are expected to present major policy or administrative issues to the MAC and BAG for consideration prior to making final policy decisions unless an urgent situation arises.

Third, we believe that CMS should consider more required roles for MAC and BAG involvement. Current regulations suggest or require consultation or communication with the MAC on several issues, including section 1115 demonstration applications and monitoring (§§ 431.408 and 431.430), managed care program reports (§ 438.66), review of managed care marketing materials (§ 438.104), development of state managed care quality strategy (§ 438.340), development of alternative managed care quality rating systems (§ 438.334), development of access monitoring review plan (§ 447.203). CMS should conform these cites to include the BAG (and the newly titled MAC).

Finally, CMS should also consider the role of the BAG more broadly. CMS should require states to leverage BAG expertise for a variety of functions, particularly those relating to beneficiary communications or surveying. For example, CMS should require states to share Medicaid application designs and notice templates (including those used for managed care) with the BAG for comment prior to completion. Consulting the BAG prior to important managed care program changes would also help ensure smooth implementation; the consumer subcommittee in Pennsylvania recently helped develop consumer-facing materials and outreach plans prior to changes in the managed care organizations operating in the state. CMS should also require that the new secret shopper processes and reports be

shared for consultation with the BAG. We believe that CMS should also require consultation with the BAG as part of the rate reduction review process described at § 447.203(c)(4). We believe CMS should make conforming changes in the proposed access rule to require BAG consultation on these issues and consider a future "request for information" process to design guidance on further uses for the BAG.

Recommendation: We recommend CMS finalize the proposed provisions with some additions. We recommend that CMS add "access to care" to the listed topics under § 431.12(g). We also recommend that CMS require states to consult with the MAC and BAG <u>prior</u> to making policy decisions and that CMS require consultation with the BAG for consumer facing communications including at least applications, state and managed care notices, enrollee surveying, and secret shopper processes. We recommend that CMS specifically include the BAG as part of the § 447.203(c)(4) rate review process. CMS should also conform existing regulatory references to MCACs to reference MAC and BAG instead.

# II. Documentation of Access to Care and Service Payment Rates (§ 447.203)

Federal law entitles Medicaid beneficiaries to medical assistance, defined under section 1905(a) of the Social Security Act (the Act) as "...payment of part or all of the cost of the following care and services or the care and services themselves, or both...". Section 1902(a)(30)(A) of the Act requires that Medicaid state plans "assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that *care and services are available* under the plan at least to the extent that such care and services are available to the general population in the geographic area" (emphasis added). Fulfilling these obligations necessitates CMS requiring sufficient provider payments to ensure beneficiaries have access to care. These standards are important to assure that people with low-incomes who are enrolled in Medicaid can access care and services they need to get and stay healthy. Ensuring that enrollees can access necessary services in a timely manner is also key to assuring that states fulfill important requirements of operating a Medicaid program, such as their responsibilities to deliver Early and Periodic Screening, Diagnostic, and Treatment (EPSDT) services to children. CMS has a unique responsibility to enforce access to services for Medicaid enrollees. The access rule proposes an updated process through which states would be required to document compliance with section 1902(a)(30)(A) of the Act and a new oversight regime for CMS to ensure such compliance.

We support CMS's proposals to promote fee-for-service (FFS) payment rate transparency; enhanced opportunities for interested parties to provide input to CMS about access to home and community-based services (HCBS); and standards for approval of state proposals to reduce or restructure FFS payment rates. We also encourage CMS to adopt additional access monitoring mechanisms for services delivered on a FFS basis in order to assure access for all Medicaid enrollees, such as wait time standards and secret shopper surveys, as proposed in CMS's companion managed care rule. Finalizing the access rule, with compliance dates as soon as is practicable, will help bring much needed transparency and minimum standards to FFS payments in Medicaid, which will help CMS fulfill its statutory responsibility to enforce access to services for Medicaid enrollees. <u>Recommendation</u>: We recommend that CMS finalize the proposed access rule provisions and additionally consider our recommendations below.

a. New regulatory framework for payment rates

Under current access regulations finalized in 2015, states are required to develop and submit to CMS an Access Monitoring Review Plan (AMRP) for certain Medicaid services that is updated every three years. The AMRP must separately analyze access to: primary care services (including those provided by a physician, FQHC, clinic, or dental care), physician specialist services (for example, cardiology, urology, radiology), behavioral health services (including mental health and substance use disorder), pre- and post-natal obstetric services including labor and delivery, and home health services, along with three types of "additional services" – those subject to a rate reduction, those for which the state or CMS has received a lot of complaints, and any additional services selected by the state. As part of the CMS approval process for rate reductions or restructuring, states must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed changes.

However, CMS guidance<sup>2</sup> and a 2018 proposed access rule (never finalized),<sup>3</sup> sent clear signals to states that rates could be reduced without consideration of the AMRP if the reductions were "nominal" or if the state had high managed care penetration rates, significantly weakening the AMRPs. In 2019, CMS proposed but never finalized a rule that would have rescinded the AMRP requirement.<sup>4</sup> At the same time, CMS issued subregulatory guidance saying the agency would establish a new access strategy later.<sup>5</sup> CMS has only posted the 2016 AMRPs.<sup>6</sup>

The proposed access rule would rescind the AMRP requirements and instead implement a new regulatory framework for access including improved rate transparency and analysis and a two-tiered system for reviewing state requests to reduce or restructure Medicaid payment rates.

<sup>&</sup>lt;sup>2</sup> CMS State Medicaid Director Letter #17-004, "Medicaid Access to Care Implementation Guidance" (Nov. 16, 2017), <u>https://www.medicaid.gov/federal-policy-guidance/downloads/smd17004.pdf</u>.

<sup>&</sup>lt;sup>3</sup> CMS Notice of Proposed Rulemaking, "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Exemptions for States With High Managed Care Penetration Rates and Rate Reduction Threshold," 83 Fed. Reg. 12696 (Mar. 23, 2018), <u>https://www.federalregister.gov/documents/2018/03/23/2018-05898/medicaid-program-methods-for-assuring-access-to-covered-medicaid-services-exemptions-forstates-with.</u>

<sup>&</sup>lt;sup>4</sup> CMS Notice of Proposed Rulemaking, "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services-Rescission," 84 Fed. Reg. 33722 (July 15, 2019),

https://www.federalregister.gov/documents/2019/07/15/2019-14943/medicaid-program-methods-forassuring-access-to-covered-medicaid-services-rescission.

<sup>&</sup>lt;sup>5</sup> CMCS Informational Bulletin, "Comprehensive Strategy for Monitoring Access in Medicaid" (July 11, 2019), <u>https://www.medicaid.gov/federal-policy-guidance/downloads/CIB071119.pdf</u>.

<sup>&</sup>lt;sup>6</sup> Medicaid.gov, "Access Monitoring Review Plans," <u>https://www.medicaid.gov/medicaid/access-care/access-monitoring-review-plans/index.html</u>.

We support CMS's proposal to replace the Access Monitoring Review Plan with the new framework proposed in the access rule. However, we recommend several improvements to the new access framework below.

<u>Recommendation</u>: We recommend CMS finalize the new transparency and rate reduction framework, subject to our recommendations below.

b. Transparency of FFS rates

The proposed access rule would (at § 447.203(b)(1)) require all states to post all FFS rates on a publicly available website by January 1, 2026.

We strongly support this proposal which will bring much needed transparency to Medicaid rates and allow a broad range of stakeholders to evaluate rates and the impact they may have on provider participation and access to care in Medicaid. Even in states with high Medicaid managed care penetration rates, the FFS rate schedule is often a starting point or factor in negotiated provider payment rates and therefore the FFS rates should be posted in all states as proposed.

We believe CMS should clarify the proposed rule to specify that detailed information showing the FFS rates by CPT code is required. Rate transparency, including any variation or adjustments based on population, provider type, geographical location or other factors will be useful to Medicaid stakeholders and researchers interested in identifying how provider payment rates impact access to care over time.

<u>Recommendations</u>: We recommend that CMS finalize the proposed FFS transparency provisions, including specifically the requirement for all states to publicly post all FFS rates. We recommend that CMS specify in the regulatory text that rates be posted by CPT code.

c. Analysis and disclosure of rates

The proposed access rule would require states to compare base Medicaid FFS rates to Medicare rates for primary care, obstetrical and gynecological (OB/GYN) services, and outpatient behavioral health<sup>7</sup> for calendar year 2025 by January 1, 2026. For certain HCBS services (personal care, home health aide, and homemaker services) that Medicare does not cover, states would be required to disclose the Medicaid payment amount, expressed as an average hourly rate, for calendar year 2025 by January 1, 2026.

We support the required analysis comparing Medicaid rates to Medicare rates. While Medicare is not a perfect comparator, we agree that it is a useful starting place because

<sup>&</sup>lt;sup>7</sup> In this comment letter we are using the term "behavioral health" to align with the terminology used in the proposed access rule and avoid confusion, however we note that CMS's companion managed care rule proposes replacing the term "behavioral health" with the more precise term "mental health and substance use disorder." We support use of the term "mental health and substance use disorder" and recommend CMS adopt this change in terminology in the access rule too.

Medicare rates are publicly available on a national basis. The comparison to Medicare will provide valuable information about Medicaid rates across the country. Meanwhile, since CMS has not tied any penalties to the findings of the analyses, there will be minimal harms created by the data. Nonetheless, we recognize that Medicare rates will likely be more suitable comparators for some services within each of the three categories than for others. We recommend that CMS adopt the comparative payment rate analysis and disclosure requirements as proposed but consider additional processes to develop more useful comparisons where Medicaid services have no equivalent Medicare rate, or are provided so infrequently in Medicare so as to not be a reliable comparison. For example, Medicare coverage of contraceptive services and pregnancy-related services may be inapposite. We recommend that CMS develop a list of unique Medicaid services and assign a different benchmark for those services. CMS could consider developing a research project, for example with the Medicare Payment Advisory Commission (MedPAC) and the Medicaid and CHIP Payment and Access Commission (MACPAC), to evaluate the missing services and set the appropriate benchmark. We further recommend that CMS develop a plan to expand analyses to all services Medicaid covers over time as the reliability and usefulness of comparison data is established.

We also support the disclosure requirements for HCBS services.

<u>Recommendations</u>: We recommend that CMS finalize the proposals for analysis and disclosure of rates in the access rule, and develop a plan to implement comparisons for all Medicaid services over time. We recommend that CMS additionally develop a comparison methodology for services that have no equivalent Medicare rate or are provided so infrequently in Medicare so as to not be a reliable comparison.

## d. Interested Parties Advisory Group

The access rule proposes to require states to establish an "interested parties advisory group" at § 447.203(b)(6). The interested parties advisory group would advise and consult with the Medicaid agency on current and proposed direct care worker payment rates along with related access to care metrics and submit recommendations to the state at least every two years. The state would be required to post the recommendations within one month of receipt. This advisory group would fill an important void – there are <u>known access issues</u> for direct care workers in Medicaid but because Medicare does not cover these services, states cannot simply compare payment rates to Medicare when considering whether payment rates are hindering access.

We support the creation of the interested parties advisory group. We believe the group should be allowed to advise and comment on a broad range of HCBS provider rates and CMS should consider leveraging the group for feedback on HCBS access issues more broadly. It is critical for Medicaid programs to evaluate rates and access for HCBS services, especially considering the unique market power of Medicaid for HCBS infrastructure. We suggest that the advisory committee be independent of the state and include sufficient representation from beneficiaries and their authorized representatives. We suggest that at least 25 percent of seats in the group are reserved for Medicaid beneficiaries or their representatives, as proposed for the BAG.

We recommend that the advisory group receive sufficient explanations and information as to how any proposed rates were calculated, in addition to the metrics required by the payment adequacy and reporting requirements sections. This information should include clear, consistent definitions of the cost elements that are considered in establishing a rate. The state should also be required to publish a public response to the advisory group's recommendations, explaining the evidence used to make their final rate recommendations, whether they accepted the recommendations of the advisory group, and if the rates differ from the recommendations, explaining the State's reasoning.

We believe that the MAC and the interested parties advisory group should be separate. They could have some overlap in membership and coordinated meetings, but the work required merits two groups. It would be unreasonable to expect the MAC to fulfill its important obligations overseeing the entire Medicaid program and the particular issues related to the direct care workforce. In addition, while the MAC draws from a very broad cross-section of Medicaid stakeholders, the interested parties advisory group will need to draw from a much more specialized set of stakeholders (for example, stakeholders with deep experience with each of a number of disabilities and functional challenges).

<u>Recommendations</u>: We recommend that CMS finalize regulations for the proposed interested parties advisory group, but keep the entity separate from the MAC. We recommend the group be independent, made up of at least 25 percent beneficiaries or their representatives, be authorized to provide advice on a broader range of HCBS payment rates, receive sufficient explanations and information as to how any proposed rates were calculated, and that the state be required to publish a public response to the advisory group's recommendations.

e. Rate reduction

Under current regulations, states must analyze access to services subject to rate reduction, and as part of the CMS approval process for rate reductions or restructuring, states must consider the data collected through the AMRP and undertake a public process that solicits input on the potential impact of the proposed changes.

As noted above, the proposed access rule would eliminate the AMRP process. For rate reductions, CMS proposes a two-tiered approach that would require rate reduction or restructuring state plan amendments (SPAs) to satisfy certain criteria to qualify for a lower level of review and require enhanced analysis and procedures for those that do not meet the criteria. The proposed criteria include written assurance and relevant supporting documentation to establish that: (1) services affected by the proposed reduction or restructuring would be paid at or above 80 percent of the most recently published Medicare rates for the same or comparable aggregate set of Medicare-covered services; (2) the proposed reductions or restructurings would result in no more than a four percent reduction in aggregate FFS expenditures for each benefit category within a single state fiscal year; and (3) there are no evident access concerns raised through public processes

set out in § 447.203(c)(4) and § 447.204. In addition, CMS proposes at § 447.203(c)(1) to establish standard information that states would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when the changes could result in diminished access.

We support the concept of a two-tiered system that CMS has established in the proposed access rule, though we recommend changes to the criteria for qualifying for a streamlined SPA approval process when reducing or restructuring rates. We believe that CMS should adjust the first two prongs of the rate reduction criteria per our recommendations below, as 80 percent of Medicare rates is too low (prong one) and four percent cuts are too high (prong two). We believe CMS's primary goal should be to encourage increasing rates to Medicare levels and creating feedback through stakeholder processes.

We support the design of prong one, allowing states to receive a lower level of review based on a Medicare payment threshold, but recommend that the threshold be raised to 100 percent of Medicare rates because Medicaid access would be improved by sustaining Medicaid rates at the Medicare level. Medicare beneficiaries report broad access to physicians, hospitals, and other providers, and relatively low rates of problems across a number of access measures.<sup>8</sup> Medicaid beneficiaries deserve the same access to care that Medicare beneficiaries experience. As the preamble states, many providers are already paid at 80 percent of Medicare and thus it seems appropriate to select a higher standard by which to assess whether a reduction would diminish access. *It is time for CMS to consistently align <u>all incentives</u> to raise Medicaid rates to Medicare levels.* We are also concerned that CMS' proposed "aggregate" standard – reviewing rates across a benefit category rather than at the service-specific level – will mean that some Medicaid services may be paid well below the percentage threshold even if the overall benefit category achieves the threshold. CMS should consider setting the threshold on a disaggregated basis to protect access to key services and avoid permitting states to obscure low payment rates.

We also believe CMS should reconsider the threshold in the second prong of analysis. A four percent reduction is a large reduction for providers to absorb, particularly in the context of a rate that is only 80 percent of the Medicare rate per CMS's proposed prong one. We recommend that the prong two threshold be reduced to one percent or lower. We also urge CMS to consider designing a limit to ensure that states could not implement a deep cut (say 20 percent) to a particular service by analyzing the service within a broader category of services which, as a whole, does not exceed the four percent (or similar) threshold. CMS could also consider disaggregating service analysis in future rulemaking.

The third prong of the criteria is critical and we applaud CMS for centering the importance of public concerns about rate reductions or restructuring when assessing whether states should be required to provide additional information to support proposed reductions. Developing robust mechanisms for states to hear feedback from providers and

<sup>&</sup>lt;sup>8</sup> Cubanaski, J., et. al., "A Primer on Medicare: Key Facts About the Medicare Program and the People it Serves," Kaiser Family Foundation (March 2015), <u>https://www.kff.org/report-section/a-primer-on-medicare-how-do-medicare-beneficiaries-fare-with-respect-to-access-to-care/</u>.

stakeholders about access concerns will be critical to assuring that this proposed provision has its intended effect. We believe CMS should further consider formalizing a specific role for the MAC/BAG in guiding the state's development of a system to collect complaints about access, in assessing whether there are significant access to care concerns, and in making recommendations to the state prior to SPA submissions. CMS should also specifically include the MAC and BAG in the rate reduction review process set out in § 447.203(c)(4).

We support CMS's proposal to establish standard information that states would be required to submit with any proposed rate reductions or proposed payment restructurings in circumstances when the changes could result in diminished access. For states that do need to conduct enhanced analysis for SPAs that could result in diminished access, we support the standards that CMS has specified in § 447.203(c)(2), including CMS's proposal to require states to submit data for the three-year period immediately preceding the submission date of the proposed rate reduction or payment restructuring SPA. We agree with CMS's proposal to maintain a number of the currently required data elements from the AMRP but to be more precise about the type of information that would be required and to require additional elements to enable CMS to assess how the proposed changes would impact access. However, we recommend the regulations require states to publicly post the enhanced analysis, including data submissions, and that CMS post the state submissions directly to guarantee full transparency.

Finally, we support CMS's proposed clarification at § 447.203(c)(3) that CMS may disapprove SPAs that could result in diminished access if a state fails to submit the information discussed above, or if CMS concludes that the relevant information points to unresolved access issues. This provision helpfully codifies CMS's longstanding authority to enforce access standards under section 1902(a)(30)(A) of the Act by denying SPAs and/or taking compliance action to protect access for Medicaid enrollees.

While we are generally supportive of CMS's approach to addressing rate reductions, we note that some states have rates well below Medicare levels and many states may change some rates very infrequently. This means that, assuming a state does nothing, currently inadequate rates could simply persist for decades more under CMS's approach (and in fact regress relative to inflation) and undermine Medicaid beneficiaries' access to needed care. The ultimate test, as laid out in the statute, is that provider payments are sufficient to ensure beneficiaries have access to medical assistance. Therefore, we recommend that CMS consider using its authority to establish, or at least encourage states towards, a national floor for rates, based on 100 percent of the Medicare payment rate.<sup>9</sup> For example, CMS could phase in an explicit regulatory norm, raising minimum FFS rates to Medicare levels over a specified period of time, or, implement standards tying use of a percentage of Medicare rates threshold (starting at 80 percent and increasing to 100 percent) in

<sup>&</sup>lt;sup>9</sup> We note that section 1902(a)(30)(A) of the Act requires payment to achieve access "at least to the extent that...care and services are available to the general population in the geographic area." Considering that Medicare rates are themselves consistently below the average commercial rate that represents the largest share of insured individuals in the country, CMS setting a Medicaid norm at least at the Medicare level should not be an impermissible interpretation of the statute.

Medicaid to approvals of related Medicaid flexibilities, such as section 1115 approvals, state directed payments implementing average commercial rate (ACR) payment levels, etc. (as CMS has already done for some 1115 approvals for health-related social needs). CMS should consider an immediate policy of requiring a state to pay all Medicaid services at least at 100 percent of Medicare levels <u>prior</u> to authorizing new rate increases for some services above Medicare levels toward ACR levels (and CMS should continue to apply this policy if its final regulation allows payment above Medicare levels).

<u>Recommendations</u>: We recommend that CMS finalize the proposed provisions on rate reductions, with some changes. We recommend that CMS raise the Medicare payment level threshold in the first prong to 100 percent of Medicare payment levels. We recommend that CMS reduce the cut percentage in the second prong of analysis to a threshold of one percent or lower. We recommend that CMS further consider formalizing a role for the MAC and BAG in the review process and in identifying access concerns and specifically include the MAC and BAG in the rate reduction review process set out in § 447.203(c)(4). We also recommend CMS's rate review be implemented at a more granular service-specific level to ensure that aggregate data does not mask deep payment gaps. We also recommend that CMS require states to publicly post any additional data submissions and enhanced analyses. Finally, we recommend that CMS use its authority to adopt or encourage a national norm for Medicaid rates, set at 100 percent of Medicare rates.

f. Additional standards for fee-for-service states

In its companion rule on managed care, CMS is proposing new access criteria which are not proposed for FFS, including wait time standards, secret survey shopper requirements, and related publication requirements for certain services.

We believe CMS should apply these requirements to all states that use FFS as a way to deliver some or all services. States may operate as fully FFS delivery systems and combination delivery systems, including combinations where certain service types or populations are covered outside of managed care (e.g., behavioral health services or people with long-term services and supports (LTSS) needs). We believe CMS should implement the new managed care access criteria for all states that use FFS delivery. States with smaller FFS programs will have some burden but an easier time coming into compliance given the size of their FFS populations. At the same time, in such states the population targeted for FFS enrollment often has complex needs requiring the strongest access protections. We support CMS applying equivalent standards in managed care and FFS, to the extent practicable, including to assess geographic variation. Medicaid enrollees have the same right to accessible services regardless of whether their state elects to deliver services via a FFS or managed care delivery system, and CMS should hold states accountable for assuring access to the same degree that CMS proposes to hold managed care organizations responsible for access.

<u>Recommendation</u>: We recommend that CMS implement wait time standards, secret survey shopper requirements, and related publication requirements in all states using FFS, to align with the managed care rule.

## III. Home and Community-Based Services

As the primary payer of HCBS in the US, Medicaid plays a critical role in meeting the needs of individuals receiving LTSS at home and in the community. Such services are particularly important for children with special health care needs – half of whom receive their care through Medicaid and CHIP.<sup>10</sup> Ensuring sufficient consumer protections and timely access to HCBS is essential to meeting the needs of children with special health care needs. We applaud CMS for efforts to create alignment for HCBS across programs (e.g., state plan services and waiver services) and delivery systems (e.g., FFS and managed LTSS). We believe it is important to create alignment and implement similar policies across delivery systems, as there should not be disparate access to care and support processes based on delivery system. In addition, though the use of managed LTSS is growing, many populations with functional challenges remain in FFS, making access improvements in both delivery systems critical.

a. Grievance System (§§ 441.301(c)(7), 441.464(d)(2)(v), 441.555(b)(2)(iv), and 441.745(a)(1)(iii))

The proposed rule would require states to establish grievance procedures for Medicaid beneficiaries receiving certain HCBS services.

We support the proposal to implement a grievance process for individuals to express dissatisfaction with the state or a provider's compliance with the person-centered planning process and the home and community-based settings rule. Individuals in FFS Medicaid must have an effective way to express grievances about compliance with these two linchpins of HCBS delivery.

We recommend that CMS shorten the timeframe for grievance resolution to 45 days. While we appreciate a 14-day expedited option for issues that pose a substantial risk to the health, safety, and welfare of the beneficiary, there are many other potential violations that may not meet that definition, but are still of critical importance to the beneficiary. Ninety days is too long to resolve potentially critical rights violations, such as denials of visitors or the inability to control one's own schedule and choice of activities. We also recommend that CMS specify that another individual or entity can represent the beneficiary throughout the entire grievance process. Beneficiaries should be able to choose their own representative to assist with presenting evidence and testimony and make legal and factual arguments related to their grievance.

<u>Recommendations</u>: We support the proposal to implement a grievance process. We recommend that CMS shorten the timeframe for grievance resolution from 90 days to 45 days and specify that another individual or entity can represent the beneficiary throughout the process.

<sup>&</sup>lt;sup>10</sup> Elizabeth Williams, et al., "Children with Special Health Care Needs: Coverage, Affordability, and HCBS Access," Kaiser Family Foundation (Oct. 4, 2021), <u>https://www.kff.org/medicaid/issue-brief/children-with-special-health-care-needs-coverage-affordability-and-hcbs-access</u>.

b. Incident Management System (§§ 441.302(a)(6), 441.464(c), 441.570(c), and 441.745(a)(1)(v))

The access rule proposes an incident management system, which includes a definition for "critical" incidents. It is imperative that states have sufficient safeguards in place to ensure that necessary care and services are provided and that such services are provided in a manner consistent with the best interests of the beneficiary. Appropriate and meaningful health and safety policies and procedures are particularly important for vulnerable populations such as children.

<u>Recommendation</u>: We support CMS's proposed incident management system, and specifically support the definition of "critical incidents," which includes incidents of verbal, physical, sexual, psychological or emotional abuse; neglect; exploitation including financial exploitation; misuse or unauthorized use of restrictive interventions or seclusion; medication errors; and unexplained or unanticipated death. We recommend that the regulation require parallel reporting to the designated protection and advocacy system when such reports are made to the state.

- c. HCBS Payment Adequacy (§§ 441.302(k), 441.464(f), 441.570(f), 441.745(a)(1)(vi))
  - i. Direct care worker wages

HCBS direct care workers are the backbone of the HCBS workforce. They perform difficult and extremely important work, yet historically, direct care services have been undervalued and undercompensated, with workers often earning low wages with limited benefits, resulting in high turnover rates and workforce shortages. Poor wages and benefits for direct care workers also raise serious equity issues given that the HCBS workforce is comprised primary of women of color. Though the demand for HCBS services continues to grow, workforce shortages have resulted in access challenges. Ensuring fair wages is critical to keeping pace with the growing demand for high-quality HCBS care, including for children with long-term care needs.

We recognize that the only way to truly satisfy the growing demand for high-quality HCBS services is to increase wages for HCBS direct care workers to bolster recruitment and reduce turnover. We encourage CMS to work with states to ensure sufficient payment rates to ensure access to services. At the same time, HCBS rate increases have not always resulted in corresponding higher wages for HCBS direct care workers. Thus, we see value in CMS requiring states to ensure that a minimum percent of wages is passed directly through to direct care workers, and *we support a state-level requirement that a percentage of total payments for certain HCBS services, such as personal care, home health aide, and homemaker services, be spent on direct care worker compensation.* 

We support a fully transparent accounting of all components of the HCBS rate structure for HCBS services to determine over time what the appropriate percentage for each service should be. As CMS develops technical guidance on the rate structure, we support the

proposal that non-billable expenses like worker onboarding, training, recruitment, travel between clients, and other workforce activities should not be counted toward worker compensation in the calculation of the percentage of HCBS expenditures that goes to direct care workers. To the extent that these non-billable expenses are necessary for an accessible, high-quality HCBS program, they should be factored into the equation as part of a reasonable estimate of the non-compensation share of the rate.

We also recommend that HHS require states to consult with beneficiary stakeholder groups, such as the proposed interested parties advisory group and the BAG, for recommendations on proposed rate structures and methodologies.

<u>Recommendations</u>: We support a state-level requirement that a percentage of total payments for certain services be spent on direct care worker compensation along with a fully transparent accounting of all components of the HCBS rate structure for HCBS services and in consultation with beneficiary stakeholder groups.

ii. State plan services

CMS requests feedback on whether to apply payment adequacy provisions to "state plan" services. and we believe they should apply, at a minimum, to state plan personal care and home health services delivered under section 1905(a) state plan authority as well as other HCBS services as identified by the Secretary.

The proposed rule excludes 1905(a) HCBS services such as personal care services and home health aide services authorized under state plan services, asserting that "the vast majority of HCBS is delivered under section 1915(c), (i), (j), and (k), while only a small percentage of HCBS nationally is delivered under section 1905(a) state plan authorities." While this may be true nationally, the use of state plan services is not uniform across populations or states.

Children who receive HCBS services such as personal care services or home health aide services should be relying overwhelmingly on 1905(a) state plan services. Under Medicaid's ESPDT benefit, children have a right to services such as personal care services and home health aide services via the state plan. CMS has repeatedly stated that in such cases, if a service can be authorized under the state plan, it may not be authorized under a waiver.<sup>11</sup> Thus, state plan services must be included to ensure that any positive changes from this rule equally benefit the pediatric population and the home care workers who serve them.

Second, while all states must provide home health aide benefits via the state plan, there is much more differentiation in how states cover personal care services. While the definition of personal care services is not uniform across authorities, these differences are inconsequential for most beneficiaries. Issues with access and quality span all authorities.

<sup>&</sup>lt;sup>11</sup> CMS, "Application for a § 1915(c) Home and Community-Based Waiver; Instructions, Technical Guide and Review Criteria" (Jan. 2019), https://wmsmmdl.cms.gov/WMS/help/35/Instructions TechnicalGuide V3.6.pdf.

From the beneficiary's perspective, there is no reason not to apply the proposed regulations to all the ways in which a state may authorize personal care services, especially if children could be disproportionately impacted.

We also recognize that other types of HCBS may not fall into the homemaker services, home health aide services, and personal care services categories listed in the proposed rule for purposes of the payment adequacy provisions. We encourage the Secretary to examine whether other HCBS services including those delivered under 1905(a) state plan authority beyond homemaker services, home health aide services, and personal care services should be included and if so, include such services in the payment adequacy provisions.

<u>Recommendations</u>: We recommend CMS apply the payment provisions to state plan personal care and home health services delivered under 1905(a) state plan authority and encourage the Secretary to examine whether other HCBS services delivered (including those delivered under section 1905(a) state plan authority) should also be included in the payment adequacy provisions and include them as appropriate.

d. Access Reporting (§441.311(d))

i. Waiver waiting lists

The proposed rule requires the state to report to CMS on section 1915(c) waiver waiting lists. The information would include whether the state screens individuals for eligibility prior to placing them on the list, whether the state periodically screens individuals on the list for continued eligibility, and the frequency of rescreening, if applicable. States would also report on the number of people on the list who are waiting to enroll, and the average amount of time individuals newly enrolled in the waiver program in the past 12 months were on the waiting list.

We support this provision. This information could help advocates, policymakers, and other stakeholders better understand unmet need in the state, and would allow individuals and families to plan for their future. However, as part of this information, CMS should require states to break the information out by age including pediatric population wait times.

<u>Recommendation</u>: We support the proposal to require states to report to CMS on waiver waiting lists, however, we also recommend CMS require states to report on the number of children on waiver waiting lists.

ii. Access to homemaker services, home health aide, and personal care

Access issues can be particularly challenging when it comes to HCBS. People who are approved for HCBS often struggle to find staff to support them, leading to *de facto* denials. Measuring the percentage of authorized hours that are actually provided is one measure of this unmet need, and we support its inclusion in the final rule.

We support the requirement to track the average amount of time from when services are authorized until they are provided and the percentage of authorized hours that are actually provided over a 12-month period. However, in addition to this metric, it is also important to track why such services were *not* provided. There are many reasons why authorized services may not be provided promptly, ranging from administrative burden and delays by the state, to a lack of providers, to access issues related to fiscal management agencies for self-directed services. Thus, it would be helpful to track reasons for such delays or failure to provide all authorized services, and to require the state to track the most common reasons why such hours were not filled. We also encourage CMS to require states to break out such reporting by age to better capture wait times for pediatric populations.

In addition, as noted above in comments on HCBS payment adequacy, and for the same reasons, these provisions should also apply to 1905(a) state plan services for home health aides and personal care services and other HCBS services as identified by the Secretary.

<u>Recommendations</u>: We support the requirement to track the average amount of time from when services are authorized until they are provided and the percent of authorized hours that are actually provided over a 12-month period, but also recommend the tracking of why such services were not provided and include break outs by age to capture wait times and other barriers for pediatric populations.

iii. Payment Adequacy

The proposed access rule would implement new reporting requirements for section 1915(c) waivers for states to demonstrate that they meet the proposed payment adequacy provisions.

We support the proposal that states report annually on the percent of payments for certain services that are spent on compensation. We agree that additional information about the median hourly wage and compensation by category would be helpful, and suggest that CMS include a requirement for such information in the final rule. This information should be stratified by delivery system and where applicable, by plan, to capture differences between managed LTSS and FFS.

The value of the information for future rate-setting purposes outweighs any burden. Agencies likely readily have this information, but direct care workers and other stakeholders may not. To allow for meaningful participation by the interested parties advisory group, information such as the median wages and compensation and historic trends should be equally available to all members of the public.

As noted above in comments on HCBS payment adequacy, and for the same reasons, these provisions should also apply to 1905(a) state plan services for home health aides and personal care services and other HCBS services identified by the Secretary.

<u>Recommendations</u>: We support CMS's payment adequacy reporting provisions and also recommend CMS stratify the information by delivery system and plan, make the information

equally available to all members of the public and apply the provisions to 1905(a) state plan services for home health aides and personal care services and other HCBS services as identified by the Secretary.

e. HCBS Quality Measure Set (§§ 441.312, 441.474(c), 441.585(d), and 441.745(b)(1)(v)

The proposed rule would make a number of changes related to reporting of HCBS quality measures including requiring states to report on core measures within the HCBS Quality Measure Set, establish performance targets, and describe the quality improvement strategies that the state will pursue to achieve performance targets for such measures. Overall, we support the proposal to develop and maintain a core set of HCBS quality measures and require regular state reporting. We also encourage CMS to ensure that the experiences of pediatric populations are represented in such measures including expanding the basis and scope of HCBS core measures quality reporting to include 1905(a) HCBS services and ensuring other data collection measures such as experience of care surveys capture the experiences of pediatric populations, as appropriate.

We encourage CMS to work towards increased reporting and alignment of the HCBS quality measure set reporting with the reporting requirements for the child, adult, and home health quality measure core sets. Such alignment would help maximize the effectiveness of the measure set for CMS, state Medicaid agencies, plans, providers, advocates, and HCBS participants and make such information more publicly actionable.

<u>Recommendations</u>: We support the development and maintenance of a core set of quality measures within the HCBS Quality Measure Set. We also encourage CMS to ensure the experiences of pediatric populations are represented across such measures and to work towards increased reporting and alignment of the HCBS quality measure set reporting with the reporting requirements of other Medicaid core measure sets.

# IV. Conclusion

We applaud CMS for its commitment to improving access to care in Medicaid and we believe the proposed rule, with some improvements, should be finalized and implemented as soon as practicable. More beneficiary engagement and public transparency will help ensure that states and CMS are meeting the statutory requirements to deliver on Medicaid's promise to provide access to high quality, affordable health care.

Our comments include numerous citations to supporting research for the benefit of the CMS. We direct CMS to each of the studies cited and made available through active hyperlinks, and we request that the full text of each of the studies cited, along with the full text of our comments, be considered part of the formal administrative record on this proposed rule for purposes of the Administrative Procedures Act.

Thank you for considering our comments; if you need more information, please contact Leo Cuello (<u>leo.cuello@georgetown.edu</u>) or Kelly Whitener (<u>kelly.whitener@georgetown.edu</u>).

Sincerely,

Joan C. Alher

Joan Alker Research Professor Executive Director