NAMD
National Association of Medicaid Directors

July 27, 2015

Ms. Vikki Wachino
Director, Center for Medicaid & CHIP Services
Centers for Medicare & Medicaid Services
Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Attn: Comments on Medicaid and Children's Health Insurance Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies and Revisions Related to Third Party Liability (CMS-2390-P).

Dear Ms. Wachino:

On behalf of the nation's Medicaid Directors, we appreciate the opportunity to comment on the proposed rule, *Medicaid and Children's Health Insurance Programs; Medicaid Managed Care, CHIP Delivered in Managed Care, Medicaid and CHIP Comprehensive Quality Strategies and Revisions Related to Third Party Liability (CMS-2390-P).* The attached comments focus on opportunities to enhance the proposed rule to ensure CMS and states can achieve our shared vision, where every state can operate an efficient program that provides high quality services to consumers and is accountable to taxpayers.

The National Association of Medicaid Directors' (NAMD) members support and share CMS' goals for this regulatory revision, which include modernizing the regulatory framework for Medicaid managed care and creating alignment with other insurance affordability programs where appropriate. In the years since the current regulation was promulgated, Medicaid managed care has changed and grown in many ways. There is a clear need to revise the existing regulatory framework to better reflect the dynamic nature of Medicaid managed care programs and the new role of this model in covering complex populations.

Nationwide, there are efforts to reorient the health care system to achieve better care, better health and lower costs. Beyond managed care specifically, Medicaid programs across the country have taken up the call to lead payment and delivery system reform. To successfully achieve this vision, a modernized regulatory framework is needed for managed care that allows states to operate in this climate of innovation. States must have the flexibility to pursue a range of innovations in order to achieve this triple aim of health reform. The rapid pace of innovation

and the various care delivery models and payment structures had not been conceived of a decade ago. Therefore, CMS' regulatory approach to Medicaid managed care must be forward-thinking and foster innovations occurring both now and into the future.

States also need the flexibility to operate their risk-based programs in a way that reflects the diversity of the program and populations served. This is a fundamental component of the program as Medicaid is responsible for the sickest, frailest and most complex and costly patients in the country. The modernized framework should also reflect that states are continuously improving their managed care efforts, and support Directors as they identify new and effective methods of plan performance oversight. Throughout our comments, we identify opportunities where additional flexibility is needed to promote effective modernization, as well as areas where CMS' proposed approach could arbitrarily limit the variability among state programs and among quality improvement strategies.

We concur with CMS' intent to promote alignment. Coherence across health insurance affordability programs could promote efficiency in the market and reduce consumer confusion. Nevertheless, that alignment cannot come at the cost of Medicaid's more integral goals of serving our enrollees, which does not always comport with other payers. There are fundamental differences between Medicaid and other payers, and alignment should be sought only where appropriate. We encourage CMS to be cautious in pursuit of this goal, and seek a final regulation that accommodates key areas where Medicaid differs from Medicare Advantage and the qualified health plans (QHPs). We identify these differences throughout our comments, noting where alignment could be a detriment to Medicaid beneficiaries.

On the other hand, we believe CMS should extend the goal of alignment to create coherence with other federal agencies that place data and reporting requirements directly or indirectly on Medicaid, such as the Centers for Disease Control, the Health Resources and Services Administration, and the Substance Abuse and Mental Health Services Administration. Alignment of this kind is missing from the proposed regulation, but could result in substantial improvements for Medicaid enrollees.

As stated above, there are a number of overarching goals of this regulatory revision that CMS and Medicaid Directors share. In addition, Directors concur with many specific provisions of the rule. In fact, a number of the new requirements are already current practice or emerging innovations in Medicaid programs across the country. We have attempted—in the attached commentary—to indicate where new provisions align with current state practice or resolve long-standing barriers. However, we have <u>three</u> overarching concerns with the revised regulatory framework that CMS puts forward, which emerge from the scope of the new requirements.

> <u>First</u>, we are concerned that the framework would require a plethora of major program changes that would increase costs to states and the federal government. Each one of the policy changes and reporting requirements in the proposed rule will require analysis,

dedicated staff time, contract amendments, and other programmatic change that will require significant resources to implement. States have limited capacity and funds to carry out these changes, and in many cases may have to redirect resources from other efforts. Health plans will also need to amend many of their internal processes and systems to align with the new requirements, which will be costly. CMS should identify ways to support states in implementing the new regulations and ways to offset the resource burden.

Due to the extensive scope of policy change in the rule, we further recommend that CMS not implement the major provisions of the regulation simultaneously, as currently proposed. Instead, CMS should use a staggered timeline for implementation that reflects the complexity of the regulation and its various parts, and overall, this staggered timeline should provide more time for state compliance. This will allow states to be more deliberate and effective in complying with the new regulations. In addition, a staggered timeline for implementation will mitigate the potential for marketplace disruption, which is more likely to result from implementing all of these requirements simultaneously. A longer, more reasoned timeline would give CMS time to more thoroughly develop its oversight framework and guidance to states. We ask that CMS consult with states on an overarching strategy on the timing for implementing the major components of this rule. In the detailed recommendations that follow, we indicate specific provisions that should be given more time before full implementation.

Second, we are concerned that CMS does not have the capacity to carry out the array of new oversight activities under the regulation. In each section of the proposed rule—from new consumer protections to enhanced rate review requirements—CMS adds new documentation and reporting requirements that it must review and approve. The sheer magnitude of this "documentation-heavy" oversight approach provides little assurance that these documents will be reviewed in a timely fashion, nor that they, in their totality, will be particularly useful to CMS in state oversight. While states are in agreement with the principles of a transparent process, Directors are highly concerned that the proposed oversight framework would substantially increase CMS' workload and delay approvals without any substantial increase in transparency, as useful information would be buried in a mountain of paperwork. Already states must often move forward without approvals or with temporary extensions when approvals are delayed. This tenuous environment threatens the ability of Medicaid Directors to operate their programs, and would undermine the goals for high-quality Medicaid managed care envisioned in the regulation. CMS must ensure it has the capacity for the newly proposed oversight activities and pare back oversight requirements that have limited value or that CMS does not have the functional capacity to conduct in a timely fashion.

Third, the overarching framework of the regulation appears to shift the balance of authority for Medicaid managed care to the federal government, driving a top-down model that runs counter to the goal of a modernized regulatory framework. This

centralized approach would require CMS to have a multitude of new staff to conduct the new oversight functions, and CMS does not have this capacity, as we note above. More importantly, the top-down approach removes the ability of states to drive innovation in managed care delivery, to fully leverage the relationship to improve plan performance, or to tailor the approach to reflect the needs and expectations of the local population. A truly modernized framework should ensure states continue to have the central role in operating a Medicaid managed care program, with targeted checks and oversight from our federal partners.

In addition to issues outlined above with the scope of the revised rule as a whole, there are two specific policy concerns that warrant specific feedback, as they fundamentally threaten the ability of states to operate their managed care programs. These include:

- **Period of 14-day fee-for-service (FFS) coverage.** We are troubled that this policy would negatively impact quality of care for beneficiaries (§438.54(c)(2) and §438.54(d)(2)). To date, states typically structure their enrollment policies such that any enrollee who does not actively pick a plan is immediately assigned to and enrolled in a managed care plan, while allowing the individual to change plans at will for a period of 90 days or more. This allows new beneficiaries to reap the benefits of care coordination and care management provided by plans. This is particularly important for pregnant women, individuals with behavioral health needs, and other high risk populations for whom it is vital to receive coordinated care as soon as possible. The proposed 14-day policy would limit access to care coordination, the broader array of services, and expanded provider networks in managed care during the period of initial enrollment. This new requirement also mandates that enrollees must needlessly go through a transition from an uncoordinated system of FFS to managed care. In many cases, this period would end up being more than 14 days due to operational realities and could as long as 30 days or more.

  The proposed 14-day period of FFS coverage is not only a detriment to care, it is an unnecessary complication. Consumers already have the benefit of a highly effective protection, which allows them to change plans during the first 90 days of enrollment without cause and can make multiple changes in that time period. Further, this policy fails to recognize that many states no longer have FFS delivery models in their program, and compliance with this requirement would require those states to create a FFS structure. Therefore, Medicaid Directors feel strongly that the requirement for a 14-day period of FFS coverage should be eliminated as it would be a detriment to the quality of care for enrollees, is duplicative of existing protections, and creates an unnecessary administrative burden.

- **Rate review process.** The rule does not address, but rather exacerbates, longstanding and growing state concern with the rate setting process. Delays in receiving CMS approval for their rates results in operational uncertainties for states and their plans, and

can defer reforms and expansions of services for enrollees and results in states and contractors assuming risks and liabilities. These delays can span years and can adversely impact contract approvals and modifications, waiver extensions, and performance measurement. Modernization of Medicaid managed care rules cannot take place without a remedy for this barrier to rate setting, which is a cornerstone of Medicaid managed care.

Instead, the agency needs to collaborate with states to outline a process for rate reviews that makes clear the authority to administer the program remains with the state, but ensures a more coherent and timely review process. This process should detail timelines and expectations for *both* CMS and states around what occurs once rates are transmitted from states to CMS. Directors urge CMS to structure this process with the goals of achieving transparency, minimizing duplication of effort, and promoting efficient reviews. Furthermore, the process should not put states at risk for the use of their rates if they followed the process outlined by CMS and provided the necessary information to support the development of their rates on time. These issues are discussed in the recommendations that follow, and were also raised in NAMD's letter on the Draft 2016 Rate Development Guide.

While we have these areas of particular concern, Directors are also pleased to see numerous positive policy approaches in the proposed rule that support the effective modernization of Medicaid managed care regulations. These policies recognize barriers contained in outdated regulations, and also reflect the variation between Medicaid programs and the need for state flexibility in this framework. These include:

- **Capitation payment for short-term IMD stays.** While we have some significant operational concerns with this new policy, Directors are pleased that the proposed rule provides new flexibility around IMD services (§438.3(u)). We appreciate this is a first step to removing a longstanding barrier to equitable access to specialized inpatient mental health and substance abuse care for Medicaid beneficiaries. While enrollees may receive physical health services in a wide range of inpatient facilities with specialized capabilities, Medicaid funds cannot be used to pay for behavioral health services in inpatient or intermediate care facilities, even if these are most appropriate setting to meet an individual's needs. In addition to preventing parity, the IMD exclusion has also increased costs to states and the federal government by requiring individuals to receive care in more expensive and less specialized settings. Therefore, we are pleased to see the opportunity to provide coverage for short term IMD stays in managed care, but emphasize that CMS must also address the serious operational concerns of posed by this section, which we discuss in the detailed comments that follow.

  This new policy begins to move the needle, but a comprehensive, patient-centered solution to the IMD exclusion is still needed in order to achieve parity in Medicaid and provide person-centered care. Parity requires access to specialized inpatient services for

those who require care that is longer than 15 days in a month, as well as for individuals served by fee-for-service delivery models. NAMD remains convinced that only a repeal of the exclusion could achieve parity, and will continue to seek this legislative remedy. In the interim, we ask that CMS consider other options that move towards a patient-centered approach to care. Ideally, this patient-centered approach would base Medicaid coverage of services on an enrollee's health care needs, as determined through the appropriate processes. But if CMS determines that a day limit is necessary, CMS should work with states to analyze the necessary data to identify the most appropriate day limit. For instance, some states have identified that a limit of 21 days for those with psychiatric needs may be more reflective of the needs of those with serious and persistent mental illness. Likewise, some states note that a limit of 28 days for those receiving substance use treatment would be more patient-centered in light of the service needs for these individuals. We look forward to further discussion on this matter.

- **Network adequacy.** We outline in our comments some additional state flexibilities in network standards, but we are pleased that the proposed approach allows for the development of state-specific standards and adequacy metrics. States are ideally equipped to understand the dynamics of their health care marketplace and how best to ensure access for the diverse population of beneficiaries they serve and provider types they utilize. More prescriptive, national network adequacy standards would hamper the ability of managed care programs to ensure access. A set of federal network adequacy standards for managed care would fail to capture the critical differences within a state's managed care products and within-state variability. These differences are necessary to meet the complex and varied needs of Medicaid enrollees, such as those with behavioral health conditions, children with special health care needs, or for long-term services and supports for people with disabilities.

In the specific recommendations that follow, we offer more detailed feedback on the issues discussed above, as well as other key elements of the proposed regulation. We have laid out our comments based on four key sets of issues: rate setting and contract standards; quality; consumer protections; and program integrity. In offering these comments, we urge CMS to keep in mind the limited time for states to review and respond to the proposed rule, as well as the challenge to accurately assess their impact, or to identify potentially conflicting or duplicative requirements.

We also remind CMS to recognize that the new requirements will impact states in very different and dynamic ways. The enclosed recommendations reflect the collective attempt to respond to the complex and lengthy regulation in the timeframe allotted. In addition, CMS should carefully consider the comments submitted by individual state Medicaid programs. While NAMD's comments represent the consensus of our members, individual state comments include additional details, areas of specific concern, and potential impacts that further clarify the issues raised in this letter.

Finally, because of the complexity of the proposed regulations and its variable impact on existing and new Medicaid managed care programs, we ask CMS to see this input as the first step in our ongoing collaboration around the implementation of a final regulation. Engagement with states is important given the short timeframe for responding to the regulation and the magnitude of the proposed changes. Therefore, states are prepared to partner with CMS to identify additional issues as they emerge, and ensure the final regulation achieves CMS and states' mutual goals of ensuring Medicaid programs deliver high quality care that provides value for consumers and taxpayers.

We look forward to ongoing work with CMS on efforts to modernize the Medicaid managed care regulations. Should you have any questions on our comments, please contact Kathleen Nolan at Kathleen.nolan@medicaiddirectors.org.

Sincerely,

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Recommendations on Medicaid Managed Care Proposed Rule

MLR, RATE SETTING AND CONTRACT PROVISIONS

In this section of NAMD's recommendations, we provide comments on the rule's requirements on the medical loss ratio (MLR), rate setting, and contracting provisions. Directors' primary concern in this area is the structure of CMS' rate review process, which will continue to be inefficient and burdensome for both the states and our federal partners without a more defined process, and a more strategic approach to documentation. We are also troubled by the new restrictions on states' ability to direct plan payments; this could be a significant barrier to the use of managed care delivery models and could impede delivery system reform.

In addition, we applaud provisions in this section of the rule that would reflect the need for state flexibility in a modernized regulatory framework in Medicaid. States are pleased with the proposal to allow capitation payments for short term stays in institutions for mental disease (IMDs) as a first step toward a comprehensive solution. Likewise, states appreciate that the MLR allows states to incorporate a wide array of activities that improve health care quality, and we call for further clarity to designate specific non-medical services that can be accommodated in the numerator of the MLR calculation.

Our comments that follow are dived into the following sections: rate review process, rate setting and actuarial soundness, contract provisions, and medical loss ratio.

Rate Review Process

1. CMS should establish a clear process for its review of rates, and institute a hold harmless policy for when CMS' approval is delayed (§438.7 et seq.). States recognize that CMS must fulfill its fiduciary and oversight responsibilities, and we are supportive of efforts to achieve the necessary transparency. However, states have longstanding concerns with CMS' rate review process, which is not well-articulated, is often inconsistent across regions, and creates a fundamental risk for states. Recently, states have experienced more frequent and significant delays in receiving CMS approval for their rates, which results in operational and fiscal uncertainties for states and their plans. For example, it can be difficult for states to hold plans accountable without the ability to pay plans according to approved rates. These delays can span years and can adversely impact contract approvals and modifications, waiver extensions, and performance measurement. In some cases, it can even cause plans to fail if actuaries identify a pressing need to amend rates, but the state cannot effectuate a change for 6 months or more.

   To remedy longstanding concerns with rate approvals, CMS should collaborate with states to outline a process for rate reviews. The framework should lay out timelines and

expectations for *both* CMS and states around what occurs once rates are transmitted to CMS. It should be structured with the goals of achieving transparency, minimizing duplication of effort, promote efficient review and recognize the strict standards within the actuarial profession.

A clearly articulated process will greatly improve the efficiency of this process, but as we reference elsewhere in our comments, CMS remains significantly under-resourced to conduct these reviews efficiently. Therefore, we seek a safety-net for when rate approvals are delayed. CMS should establish a hold harmless policy when states meet rate submission requirements but CMS fails to approve rates in a timely manner. In these cases, if CMS fails to approve rates within 90 days of their submission date, states should be permitted to use proposed rates and be held harmless for their use until CMS approval is received.

2. To ensure rates are based on timely data and plan experience, states should be required to submit rates and contracts no more than 45 days prior to effective date (§438.3(a) and §438.7(a)). States are committed to working with CMS to meet appropriate timeframes for rate submission to help ensure the process is more predictable with regard to the timing of approvals and effective dates. However, we are concerned about requiring rates and contracts to be submitted 90 days in advance of the effective date. The proposed 90 day requirement for rate submission, when coupled with the necessary time to develop the rates, would result in states using data that is less timely, which raises concerns with accuracy of developed rates. Actuaries at the state level generally take 60 days or more to conduct their analysis and establish rates. For states to meet the proposed 90 day state submission deadline, the data used for rates will be almost six months old by the time of the contract effective date, at a minimum. States believe 45 days is a more appropriate timeline for rate submissions and would ensure that the data used to develop rates promotes accuracy and reflects current conditions.

   This alternative timeline for CMS review should be sufficient, given that CMS has sought to articulate its expectations for rate submissions in its 2016 Rate Development Guide and in this proposed rule. We believe extensive negotiations are unnecessary when states have considered all elements required by CMS, provided the necessary information on rate development, and received certification from the state's professionally trained and licensed actuary, as required. The increased transparency described in other parts of the regulation should mean that CMS' review process could be completed in the 45 day timeframe.

3. CMS should strike a reasonable balance with documentation requirements to promote transparency and align with a professional review of rates (§438.7(b)). We believe CMS's documentation requirements for its rate reviews should be designed to promote transparency, but also minimize the burden follow-up and respect the professionalism of state actuaries and their rate certifications. We believe the NPRM and the 2016 Rate Development Guide would require an unprecedented amount of documentation, which is more akin to an audit process for rates, rather than a review of the rate development

process. Overall, the proposed approach reduces the rate development to a purely formulaic process, which makes it more difficult for actuaries to develop the most appropriate rates by balancing all relevant considerations and exercising appropriate actuarial judgment. In addition, requiring this level of documentation undermines the rationale for securing the services of professional actuaries to develop rates and certify them. The volume of information may also exacerbate the unrestricted follow-up questions that have impeded timely rate approvals to date.

In addition, without additional staff capacity, CMS is unlikely to have the ability to thoroughly review the array of information and data required under the draft guide. Thus, the documentation will limit transparency by overwhelming the agencies in their review of rate submissions and will make it difficult to identify areas of concern. States stand prepared to support CMS in identifying a reasonable balance in the level of documentation required that would ensure CMS oversight of a feasible rate review process. The goal of this process should be to identify the documentation and data sources most pertinent to CMS's rate review activities, thus facilitating targeted information submissions by the state and ensuring an efficient, effective rate review.

Rate Setting and Actuarial Soundness

4. Rather than adding new restrictions on supplemental and directed payments, CMS should seek to promote transparency around their use (§438.6(c)). The NPRM would greatly limit the use of supplemental and directed payments in Medicaid managed care by establishing a new framework of conditions around these payments. We are deeply troubled that this creates inequality in the use of supplemental payments in managed care compared to fee-for-service programs. By making it more difficult to use supplemental payments in managed care, it would dis-incentivize the use of this delivery model. Medicaid Directors are opposed to policies that would discourage the use of managed care generally, or limit the full functionality of Medicaid managed care in driving quality and value for Medicaid beneficiaries.

   These payments are also a mechanism for states to reform their delivery systems and reward value over volume. CMS' regulatory approach could inhibit state flexibility to produce the next generation of transformative innovations. These new restrictions could also create the potential for a major destabilizing of some state health care delivery systems, and it would be inappropriate for CMS to eliminate mechanisms that CMS has long permitted states to leverage in their managed care delivery models. For instance, some states use these mechanisms to ensure access to critical safety net providers.

   Rather than restricting the use of supplemental payments in broad and inappropriate ways, CMS should pursue alternative approaches to promote transparency around these payments. This will help the agency achieve its policy goals around this mechanism, while

ensuring the policy is not a barrier to the use of Medicaid managed care or other innovation.

5. If CMS insists on implementing the proposed limits and conditions on supplemental payments, it must ensure sufficient flexibility to permit innovative delivery models, promote access and reward quality (§438.6(c)). Across the country, Medicaid programs are seeking to reward value and high quality care for Medicaid beneficiaries through strategic contracting with managed care plans with specific payment requirements. To support these efforts, it is vital that states be able to direct plans' payments to providers around a broad set of ideas for supporting innovation and quality, including access to high quality care. This includes, but is not limited to, value-based purchasing.

   This category should be defined more broadly than value-based purchasing to encompass the range of innovative payment approaches and other mechanisms to improve access to high quality care. For example, the enhanced payment for certified community behavioral health clinics (CCBHCs) may not necessarily be classified as value-based purchasing, but is an innovative approach to improve access and enhance the delivery of quality care. Likewise, CMS should permit innovative approaches that safeguard access. One way states promote access to quality care is by setting a floor or a ceiling for appropriate payment rates to providers. This allows plan flexibility but permits the state to set guideposts for plans that ensure access. As such, these models and others that enhance quality and access should be permitted under the rules governing supplemental payments. Further, the innovation category of supplemental payments should also be defined broadly enough to account for future innovations.

   In addition, when considering innovative models, states need to be able to direct plan payments to providers of specific services, as well as to specific delivery system models. The framework proposed at §438.6(c)(i) should be more explicit in granting this authority. For example, a state may use a health home model to deliver coordinated care to women with high-risk pregnancies. To implement this model, states may direct plan payments to these health homes.

   CMS should also explicitly allow innovation payments to providers to reflect performance and/or quality within a provider group. Section 438.6(c)(2)(i)(B) describes that states must "direct expenditures equally, and using the same terms of performance, for all public and private providers providing the service under the contract." This statement seems to run counter to the idea that within a provider group, expenditures could reflect performance and/or quality. At a minimum, the language should be revised to say a state can "directs expenditures using the same terms of performance for all…" The deletion of the word "equally" is an important nuance and is the same terminology used in §438.6(c)(2)(ii)(A).

6. CMS should limit the magnitude of rate ranges to 5 percent above or below a target base rate, rather than eliminate the use of rate ranges all together, as the NPRM proposes (§438.3(c)). States are concerned that the proposed language requiring individually-certified

capitation rates to be submitted for approval, rather than rate ranges, restricts states' ability to support innovative rate setting methodologies. CMS expresses concern that rate ranges may be used by states to make material changes without approval. While we recognize this concern, CMS' approach of eliminating their use runs counter to standard and accepted practices in the actuarial community, and would exacerbate existing concerns with the lengthy rate review process by triggering the need for a new CMS approval whenever a small rate change is needed. Consequently, it restricts the ability of states to accommodate market shifts during a contract year. It is also a broad-brush solution to a concern that could be effectively addressed through a more targeted policy change.

We propose instead that CMS consider placing outer bounds on the rate ranges. This would remedy CMS' concerns while providing states the necessary flexibility for rate setting. Specifically, we propose that CMS adopt a maximum rate range of 5 percent above or below a target rate. States with approved rate ranges within this bound could then modify the plan rate within the range, without triggering a new CMS approval process.

7. The corrective action plan for base rate setting data should, at a minimum, allow for data issues to be resolved in three years rather than two years, with additional flexibility for longer corrective timeframes on a case-by-case basis (§438.5(c)(3)). The proposed rule would require states to use the three most recent and complete years of data to develop rates for the populations being served. While the NPRM provides an exception to this, states that receive an exception must complete their corrective action plan in two years. States believe there will be numerous situations that will require exceptions to this requirement and that two years is insufficient to carry out a corrective action plan. For example, states may need an exception when expanding Medicaid to childless adults due to lack of data on this population. In these cases, it may not be feasible get three years' worth of data in two years, no matter the action plan developed. As such, a three year corrective action plan is a more appropriate timeframe. We also believe flexibility should be included to provide longer corrective action plans on a case-by-case basis, as the situation may warrant.

8. We support the principle of transparency of rates as long as it promotes the expedited review of rates and respects actuarial practice (§438.4). We agree with CMS that actuaries should be expected to meet all of the requirements of their profession and national standards. As such, we agree with the principle of transparency, which is articulated in the proposed rule. Nevertheless, these new requirements should serve to expedite the processing of rates, not to slow it down with excessive review—as we describe in Recommendation 3.

9. CMS should permit states to have different rate cells for populations with similar utilization costs, regardless of an FFP associated with that population (§438.4(b)(1)). The proposed rule appears to prohibit the use of different rate cells based on the FFP associated with a particular population. States are concerned that this provision could be interpreted in a way that would inappropriately prohibit the use of rate cells for populations that often have

unique sets of needs and costs, such as childless adults under the Medicaid expansion. The fact that the FFP is different should not prevent the unique costs of a population from being reflected in rates. This would be inconsistent with actuarial practice and would inhibit the appropriate development of rates in risk-based programs. Rather, states must be permitted to develop rate cells for unique populations, regardless of any correlation with a given FFP. CMS should also clarify how states would demonstrate that a rate cell is not based on FFP but on the unique costs of the population.

10. Any prohibitions on cross-subsidization of rate cells should be more clearly defined and more closely aligned with actuarial principles (§438.4(b)(4)). Our concerns with this provision are similar to the issues with the prohibition on basing a rate cell on FFP (see Recommendation 9 above). First, the goals of this prohibition and the issues it seeks to address are unclear. It would be helpful for states to better understand the concerns CMS is seeking to remedy through this policy. In addition, a strict reading of this provision is inconsistent with actuarial principles. For example, states often develop individual rates for each cell but use plan information and financials to inform all rate cells. This is accepted actuarial practice. Finally, it is unclear how states could practically demonstrate that rates are not cross-subsidized, and there does appear to be a feasible approach to identify and ameliorate what CMS may consider to be issues of cross-subsidization. Therefore, to address these concerns, CMS should more explicitly spell out the rating practices intended to be prohibited by this provision or eliminate it entirely.

11. States should be permitted to determine what portion of the withholds are "reasonably achievable" and may be included in the capitation rate (§438.6(b)(3)). States use withholds from capitation rates as a key tool to drive quality improvement and performance in Medicaid managed care plans. States are also best-positioned to determine the portion of any withholds that are reasonably achievable. Directors understand the quality improvement efforts plans may be tasked with addressing, as well as the plans' capacity to address them. CMS should defer to the state actuary's judgement on reasonably achievable performance withholds and refrain from impeding state negotiations and contracting with their plans via these withhold mechanisms.

12. States should have the flexibility to make graduate medical education (GME) payments directly to providers and not be required to account for such payments in their plan capitation rates (§438.6(b)(4)). CMS proposes that states that make GME payments to providers must adjust their actuarially sound capitation rates to reflect such payments. Though this is current practice in some states, other states do not require their plans to make such payments and may make GME payments directly to providers. Incorporating GME payments into the rate setting process would be inappropriate and burdensome for these states. CMS should allow states to continue making direct GME payments to providers if they so choose.

Contract Provisions

13. CMS should remove the language around outpatient drug coverage at §438.3(s)(1) or reframe it to reference existing requirements under Section 1927. It is our understanding that no new policy is being introduced in the covered outpatient drug provisions in this section of the proposed rule. However, we are concerned the inclusion of this language in the NPRM could inadvertently limit states' actions around prior authorization and off-label use of outpatient drugs, as well as shift costs onto the state. As such, we urge CMS to either remove this language entirely or reframe it to simply reference the existing requirements under Section 1927, rather than adding confusion and lack of clarity to the contract requirements around outpatient drugs.

14. We support the requirement for MCOs to identify 340B claims, but ask that CMS and HRSA collaborate with states to provide clear, coordinated guidance for plans and 340B covered entities around this provision (§438.3(s)(3)). We believe this new reporting is a step in the right direction toward addressing the interaction of the 340B drug discount program and Medicaid drug rebates. However, there are numerous technical issues that need to be addressed to achieve the identification of 340B claims. These challenges are outlined in NAMD's May 2015 whitepaper on the 340B drug discount program.

    In implementing this option, CMS should give states the explicit authority to also require plans to separately report drug claims that are subject to the discounts under the 340B program. States may find it necessary to collect all drug utilization encounters from MCOs, including 340B claims, to promote appropriate oversight of the plan and to ensure a consistent 340B claim identification process.

15. We support the use of coordination of benefit agreements and claims crossover process for plans serving dually eligible population, but seek clarification that states could pursue alternative arrangements (§438.3(t)). States support coordination of benefits and the seamless delivery of services for dually eligible beneficiaries, though Medicare's automated claims crossover process may not be the only solution for every state. Because of this, states should have the option to require their managed care entities to sign Coordination of Benefits Agreements with Medicare or require alternative approaches for achieving care coordination and cross-over claims processing.

16. We applaud the new IMD flexibility as a positive step toward parity, but urge CMS to ensure the provision can be operationalized by eliminating the expectation for recoveries and revising the IMD rate setting approach (§438.3(u)). Medicaid programs have long been concerned that the payment exclusion on institutions for mental disease (IMDs) is a barrier to ensuring enrollees receive equitable access to behavioral health services. While enrollees may receive physical health services in a wide range of inpatient facilities with specialized capabilities, Medicaid funds cannot be used to pay for behavioral health services in

inpatient or intermediate care facilities, even if these are most appropriate setting to meet an individual's needs. The longstanding concern around the IMD exclusion has also increased costs to states and the federal government. Under current policy, when inpatient services are needed, states have to provide these services in community hospitals and emergency rooms. These settings are significantly more expensive than services provided in specialized IMDs, and harm care coordination efforts. CMS's proposal to provide states with the flexibility to pay for services delivered in inpatient or intermediate care settings is a welcome acknowledgement of this long-standing issue, and states are receptive to this approach.

However, there are several operational issues raised by the current proposal which could substantially harm the feasibility of the approach. These include:

- **Recouping IMD capitation payments.** The preamble indicates capitation payments may not be made if a beneficiary's IMD stay is 15 days or more in a given month. This suggests that a state will be required to both monitor beneficiary IMD stay lengths on a monthly basis, and if such a stay lasts 15 days or longer in a month to seek recoupment of its total capitation payment made to the plan for that month. Requiring states to recoup capitation payments made to plans for beneficiaries with IMD stays that exceed 15 days will require significant retroactive adjustments and create major financial uncertainty for plans. It would also generally disrupt program operations. For example, it will be problematic to get the necessary information from plans quickly enough to operationalize recoupment. It is also unclear how states would track stays of less than 15 days, as well as set actuarially sound rates in light of the recoupment policy. Rather than requiring recoupments, CMS should ensure that states have reporting requirements and appropriate compliance actions in their plan contracts to enforce this IMD provision. Another approach might be to require a hard limit on the number of IMD days included in the state's monthly capitation payment but allow individuals to continue to be enrolled in care coordination in the event that an individual's stay exceeds 15 days.

- **Setting the capitation rate for IMD services.** To ensure the feasibility of this IMD option, CMS should allow states to price inpatient psychiatric services based on their costs in IMD settings. In the proposed rule, CMS notes that states may not use the costs of IMD services to set the capitation rate for this option. Instead, states must price these in lieu of services consistent with the cost of services delivered by providers in the state plan. This fails to address a one aspect of our concern with the IMD exclusion: it increases costs to states and the federal government by requiring care be provided in more expensive community hospitals. CMS' proposed pricing approach also runs counter to the current pricing approach to in lieu of services for IMDs, which bases costs on the IMDs, and not the more expensive community hospitals. As the rule acknowledges, it also differs from CMS' approach to HCBS in lieu of services.

17. We continue to urge CMS to pursue a comprehensive, patient-centered solution to the IMD exclusion to achieve parity for behavioral health services in Medicaid and meet beneficiaries' needs (§438.3(u)). This newly proposed policy is a major positive step toward ensuring equitable coverage of specialized inpatient psychiatric and substance use disorder services in Medicaid. However, the policy in the proposed rule is not a comprehensive solution, and the IMD exclusion will continue to be a barrier to equitable access to inpatient behavioral health services in Medicaid. We expressed these concerns in our June 8 letter to CMS on proposed rule that would apply parity in Medicaid.

    As we note in our June letter, achieving parity requires access for people with mental illness or substance use disorder to Medicaid-covered, medically necessary treatment and rehabilitation in specialized residential treatment settings with more than 16 beds. This includes individuals who need care in these specialized facilities for more than 15 days in a month. While 15-days is preferable to the current situation, we are concerned that it will arbitrarily restrict care without regard to the patient or their individual treatment needs and is not patient-centered. This arbitrary cap could result in patients being discharged prematurely, leading to increased recidivism and lack of stable care. In addition, the new IMD flexibility does not achieve parity for beneficiaries served in fee-for-service arrangements, which are left without access to specialized inpatient behavioral health services.

    To achieve parity in Medicaid, a full repeal of the IMD is necessary. In the interim, we urge the Administration to identify a range of additional steps toward a more patient-centered solution to this parity issue. Ideally, this patient-centered approach would base Medicaid coverage of services on an enrollee's health care needs, as determined through the appropriate processes. If CMS feels that a day limit is necessary, CMS should consult with states to analyze data to set the most appropriate policy that reflects the needs of the patient population. For example, some states have identified that 21 days is more reflective of the needs of individuals with significant mental health needs, including those with developmental disabilities. Others have noted that a limit of 28 days for those receiving substance use treatment is more consistent with service needs for this population and would be a more patient-centered policy.

18. States using existing "in lieu of" authority to cover IMD services should be permitted to continue using the authority as currently authorized in approved contracts and waivers (§438.3(u)). States currently using "in lieu of" authority to allow plans to cover IMD services should not be restricted in their ability to deliver services under the proposed guidance, which would be a step backwards from achieving parity. They should be permitted to retain any existing arrangements around these services, while also applying any new policy opportunities around the IMD exclusion. This will minimize disruption in those states where this has become the established practice. It will also ensure populations that are not currently covered by their existing in lieu of authority in these states can benefit from the new flexibility.

At a minimum, if CMS does not permit existing state "in lieu of" arrangements to continue, then these states should be provided with a reasonable transition period of at least 3 years to adjust their contracts, rates, and engage with beneficiaries and stakeholders to ensure there is minimal disruption in coverage service delivery.

19. CMS should clearly state that LTSS are an allowable covered service under capitation payments (§438.3(c) and §438.3(e)). The proposed text is ambiguous whether CMS has provided clear authority for provision of LTSS in capitation rates. To ensure this authority for states is clear, CMS should explicitly note in §438.3(c) or (e) that LTSS can be included in capitation rates, rather than by simply referencing the contract requirements.

Medical Loss Ratio

20. States should have the explicit flexibility to include non-medical services in the calculation of quality improvement activities in the MLR (§438.8(e)(3)). The Medicaid population differs significantly from populations covered by private insurance and Medicare Advantage, and Medicaid service packages include many benefits not covered by other insurance programs. The proposed rule states that quality improvement activities may be included in the numerator, and this is a key step toward recognizing the unique nature of Medicaid and the population we serve. While the proposed inclusion of quality improvement activities applicable to private insurance found at 45 CFR §158.150(b) is welcome, the language should give states explicit flexibility to delineate which non-medical services are considered "activities that improve health care quality."

    Medicaid's unique service packages contain many non-clinical benefits which can improve the quality of services received by a beneficiary and are critical to ensuring optimal outcomes for populations with complex needs. This is particularly important for those in MLTSS programs, where there are an array of services that promote quality, such as job coaching, housing transition supports, and coordination activities that promote community integration. States are best positioned to determine which of these non-medical services are functioning as quality improvement activities in their program and for the populations served. Therefore, the final regulatory language must explicitly allow states to define the quality improvement services that would be included in the numerator. It should also provide illustrative examples of the kinds of supports that can be permitted in this state definition, such as coordination activities that promote community integration. Further, state flexibility to define this element of the MLR will also ensure that the program can account for future unforeseen innovations in non-medical services that serve as quality improvement activities.

21. We support approaches that incentivize plans to build and maintain robust fraud prevention programs, such as including a portion of program integrity expenditures in the numerator of the MLR (§438.8(e)(4)). Allowing a portion of program integrity expenditures

to be included in the numerator recognizes that states and plans often classify program integrity investments and ongoing activities as a quality initiative. For instance, data analytics and similar integrity-focused activities serve to protect the health and welfare of enrollees. Further, the agency should ensure there is sufficient clarity around this element of the MLR in the regulation. In addition, we believe the calculation of these activities should not be limited to the program integrity activities specified in the regulation (§438.608(a)(1) through (5), (7), (8), and (b)). States should be able to specify what additional program integrity activities, which may be required by the state, can also be factored into this portion of the MLR numerator.

22. States should have the option to require different MLRs within the same contract for different eligibility groups and programs, while meeting the minimum MLR of at least 85 percent (§438.8(i)(1)). The proposed rule would allow states to require separate reporting and a separate MLR calculation for specific populations, but it would prohibit states from applying different MLRs for various populations covered under the same contract. Some states currently require different MLRs for various eligibility groups under the same contract. States may also seek to leverage multiple MLRs to account for various programs within a single risk-based contract. CMS should give states the option to 1.) apply one MLR or 2.) use variable MLRs across different eligibility groups and programs under a comprehensive contract, but which still require the plan to meet the minimum 85 percent requirement for each group or program.

23. NAMD supports flexibilities in the proposed MLR requirements that help account for fundamental differences between Medicaid, Medicare and commercial insurance. Most federal Medicaid statutory and regulatory requirements are not applicable to other public programs and insurance products. As such, the flexibilities in the proposed MLR are necessary to reflect the structural and operational differences that exist between programs, as well as the care management activities that support the unique, varied, and high-needs of Medicaid populations. We are supportive of the following provisions, which help to ensure that an MLR can be appropriately applied in Medicaid:

    - The option for states to exclude new plans from an MLR calculation for their first year of operation.

    - Allowing states to choose whether remittances from plans or other penalties should be collected for failure to meet specified MLR thresholds.

    - The ability for states to choose the 12 month MLR reporting period in order to align with their contract years, state fiscal years, calendar years, or other periods.

    - Allowing states to set MLRs higher than 85 percent to encourage high plan performance for specific Medicaid populations and programs.

24. CMS should ensure that the credibility adjustment will be sufficiently flexible to support state delivery system innovations, such as accountable care organizations (ACOs) or ACO-like entities, which may be treated as plans under the proposed rule (§438.8(h)). As states work to reform their delivery systems to meet the needs of beneficiaries, including persons with co-occurring behavioral health needs and chronic health conditions, they may utilize small, targeted plans or plan-like entities. The credibility adjustment in the MLR, as developed and applied by CMS, should support these targeted approaches and innovations by ensuring the MLR does not unduly burden or eliminate the possibility of these innovative delivery models. NAMD recommends that CMS work with states that have or are launching these kinds of innovations to ensure they are not unduly disadvantaged.

25. CMS should provide a minimum of 2 years after the publication of the final rule for states to develop and implement MLR methodologies (§438.8(b)). We are concerned that the proposed implementation timeline for the MLR calculation, which would begin in contract year 2017, is not reasonable, especially for states not currently applying an MLR. States will have to develop their MLR methodologies and make administrative changes in order to come into compliance with this provision, and will require a reasonable transition period in order to do so.

QUALITY

Medicaid Directors share CMS' goal of promoting and safeguarding quality in Medicaid, and doing so in a way that creates coherence across fee-for-service and risk-based models. Our comments focus on the provisions that could be enhanced to support state quality improvement efforts. First, we emphasize the need for measure alignment across Medicaid delivery models, as well as alignment with other programs in which Medicaid is a prominent payer. We also ask CMS to establish clear mechanisms that would allow states to develop their own quality rating systems, recognizing states are ideally positioned to shape such systems in the context of their programs. Finally, we reiterate the opportunity for CMS and states to partner to develop a menu of focused, high-value metrics that reflect population health and innovation efforts.

Our comments are divided into the following sections: measure alignment, quality rating system, comprehensive quality strategy, quality measures and performance improvement projects, accreditation or state review of plans, and external quality reviews/external quality review organization.

Measure Alignment

26. Measure alignment should be articulated as a key objective under the final regulation, including measure alignment across Medicaid managed care and fee-for-service (FFS), as well as alignment with other programs for which Medicaid is a major payer (§438.330(a)(2)). Under current policy, there are a number of areas where states have identified a lack of alignment in quality measure requirements, which is a barrier to state efforts to drive quality improvement. This misalignment exists between measures in FFS and managed

care, as well as with other programs where Medicaid is a major payer. For example, a Medicaid managed long-term services and supports program for dual eligible beneficiaries may be required to report on substantially different quality measures than a program administered by the state's office of aging, which serves much of the same population. Another example is the differences between the Medicaid meaningful use incentive program and other measure sets, such as the child and adult core sets. This hinders the movement toward effective use of EHRs.

In order to drive value in Medicaid, measure alignment should be a driving principle under the final regulation. Any performance measures for Medicaid managed care should align with existing measure sets to the greatest degree possible. This will ensure that states can adequately assess performance and outcomes across Medicaid delivery models and drive improvement across the care continuum. States are ready to support CMS in facilitating this alignment, including through the development of a menu of managed care performance measures, which we discuss in depth in the recommendations that follow.

27. CMS should provide sufficient flexibility to allow states to align measures with other payers, as appropriate. Some states may identify an opportunity in the context of their program and state reform efforts to align quality measures with other payers. These multi-payer efforts can be specific to a service type or delivery model, or can be more global in nature. Alignment will not be feasible or appropriate in all states, but the framework that CMS finalizes should not preclude this kind of activity or arbitrarily limit Medicaid's participation in multi-payer reforms. Rather, it should be flexible enough to permit states to use common measures across payers when the state deems it appropriate.

Quality Rating System

28. CMS should partner with states to develop a clear pathway and approval process for the use of alternative quality rating systems (§438.334). States believe there is value in the development and use of a quality rating in their programs. However, states are concerned that they may be limited to the CMS-developed approach under the proposed rule if CMS does not provide an explicit pathway for approval of an alternative system.

While the Medicaid quality rating system required under §438.334(a) may be appropriate in the context of some managed care programs, it will not be able to account for the differences across all state Medicaid programs and the subpopulations enrolled in risk-based entities. For example, an entity contracted to serve a state's aged, blind, and disabled population would have substantially different features than an entity designed to serve a Medicaid expansion population, and therefore must have a different, more tailored quality framework. The challenges of a one-size-fits-all approach are clearly evident from the application of the national Star Rating system to Medicare Advantage dual-eligible special needs plans (D-SNPs). This system does not adequately account for the complexity and diversity of the Medicaid population, and fails to accurately reflect quality for those with

low socio-economic status. Likewise, a CMS-developed quality rating system could not appropriately capture the unique features of risk-based programs that deliver MLTSS.

To date, many states have developed and implemented their own systems with considerable success. States understand the needs of the populations served and the features of their Medicaid programs. Because of this, the final rule should more explicitly provide states with a pathway to receive approval for and implement an alternative system (§438.334(c)). Specifically, it should articulate CMS' intent to partner with states to outline the criteria for approval of state-developed alternative systems and to outline the approval process for their use. This collaboration could take place following the promulgation of the final rule and in synch with the work to form the CMS-developed quality rating system required under 438.334(a).

29. The regulation should explicitly prohibit the use of quality ratings as the basis for CMS to incentivize or penalize plans (§438.334). Due to the fundamental differences that exist across plans and populations, it would be inappropriate for CMS to use its quality rating system– or state developed alternative systems–as the basis for CMS financial penalties or incentives for plans. While we support the use of these systems to promote transparency, they are not a sound basis for financial action. Such action would adversely impact the health care marketplace and plan landscape, and would be a barrier to payment and delivery reform states are driving in Medicaid. Decisions regarding financial rewards or penalties for plan performance on quality metrics are best left to the states via contracting with their plan partners, as CMS recognizes elsewhere in the proposed rule at §438.6.

30. We support CMS' plan to engage key stakeholders in the development of a CMS-developed quality rating system and believe states should be CMS' primary partner in this process (§438.334). States are pleased that CMS intends to engage with stakeholders in the development of a quality rating system, and we ask CMS to look to states as their primary partner in the development of this system. States have critical experience that should inform the practicality and utility of such systems as they understand the fundamental differences between programs and populations. This state engagement will be imperative in the event that CMS does not provide a clear path for states to develop and use their own system. States are also the only equity stakeholder that would be participating in this process with CMS.

31. States agree that a 3-5 year period is necessary for the implementation of CMS' quality rating system, as well as new state-developed systems (§438.334). As CMS acknowledges in the preamble of the proposed rule, it will take time to refine the quality rating system that it intends to put forward. We agree that this is a major undertaking and believe 3-5 years is an appropriate timeframe for its development and refinement. This timeframe should begin once the final criteria for the CMS rating system, as well as the path forward for an alternative system, are published by CMS in order to provide sufficient time for implementation.

32. The CMS-developed quality rating system should permit adaptations to account for basic differences in programs and goals (§438.334). As noted above, we support the use of quality rating systems in Medicaid, but believe states should be permitted to take up their own system or adopt the CMS-developed approach. In those cases where states default to CMS' approach, it is still important that this system contain mechanisms that will allow it to account for some of the basic differences between programs and populations. Otherwise, this quality rating system will not be reflective of high need populations in managed care and will not provide any meaningful quality comparisons across plans. In addition, these flexibilities will be particularly important in the event that CMS does not give states a clear pathway to receive approval for an alternative quality rating system.

    Flexibilities in the federally-developed approach should include:

    - The use of state-identified measures, in addition to the federally-specified measures. This will help tailor the model to the key quality concerns in the state program (§438.334(a)(3)).

    - Targeting quality rating based on geographic regions. Some states focus their quality improvement efforts on key concerns in a given region of the state, for example, focusing on infant mortality in certain state zip codes where this is a pressing concern.

    - Permitting the use of measures generated entirely from administrative claims data as alternatives to measures that would require a review of denied claims. This option is particularly important for states that do not receive denied claims from plans nor have the resources to conduct chart review.

    - Allowing states the flexibility to use alternative measures and methodologies in the CMS-developed system when aligning with multi-payer quality efforts in the state or for other reasons targeted to an individual state's quality improvement efforts.

Comprehensive Quality Strategy

33. States support the requirement to create a comprehensive quality strategy, but urge CMS to collaborate with states to support its implementation and to provide an adequate phase-in for its development and deployment (§431.502 and §431.504). States share CMS' strong commitment to drive quality improvement in Medicaid and believe the proposed quality strategy has the potential to be a tool to promote value across the program. To ensure that the strategy drives improvement and is not simply an administrative burden, CMS should collaborate with Medicaid Directors to develop the framework for this strategy following the release of the final rule. This framework should ensure that a state's quality strategy is meaningful and feasible.

Once the framework is laid out, CMS should also provide resources to support the state adoption of a quality strategy. Various tools and resources could include a list of questions for state consideration, which CMS has provided to states around their managed care quality strategy in previous years. CMS should also make available one-on-one technical assistance for those states that request it. This assistance should be available both for states with existing quality improvement strategies and states adopting this type of strategy for the first time. It is also important that CMS have the capacity to support states in this effort.

Finally, we urge CMS to provide 24 months following the release of supporting tools for states to create this comprehensive strategy. The process laid out in the proposed rule will require significant effort to develop. States will have to conduct analyses to identify specific quality metrics and performance targets for measuring improvement. It will also be time-intensive to collect and incorporate public input, as well as input from CMS on a draft strategy. While states are conducting these activities, they will also be implementing other elements of this regulation, which will strain limited state resources.

34. CMS should articulate the agency's process and timing for providing input and feedback on draft comprehensive quality strategies. In the past, states have faced significant delays in receiving input on managed care quality strategies. Because of this, states are concerned that CMS has not specified a process or timeframe for providing input on the comprehensive quality strategy. Without clear expectations, this step in the strategy development could delay its implementation and ultimately be a barrier to its usefulness.

35. Updates to the quality strategy should be required once every three years, but when possible, should be aligned with changes to federal quality strategies (§431.504(b)). We share CMS' commitment to ensure that this quality strategy reflects the programs and populations being served. As such, we agree that states should have flexibility to provide updates to the document when there are major programmatic changes (i.e., changes affect a significant portion of the covered population or major changes in payment methodology), and at least once every three years. Providing states with this discretion recognizes that changes in the program may occur at different intervals and due to different factors. Further, where possible, CMS should permit states to align the timing for updates to states' comprehensive quality strategy with changes in the National Quality Strategy and the CMS Quality Strategy. CMS should identify opportunities to do this, and if necessary, provide flexibility around the three year update requirement.

36. Updates to the comprehensive quality strategy should not automatically trigger an evaluation of the document's effectiveness or stakeholder consultation (§431.504(b)). To ensure that states can treat their strategy as a "living document," we ask CMS to clarify that not all updates will trigger a review of the strategy's effectiveness or the extensive stakeholder consultation envisioned under the NPRM. This would create an undue administrative burden and minimize the value of this strategy. Rather, the effectiveness

review and stakeholder consultation should only be required at states' discretion or at least once every three years.

Quality Measures and Performance Improvement Projects

37. States should be permitted to select and report on a minimum number of plan performance measures from among a menu of CMS-required measures. The minimum number of measures should be limited, and the menu should focus on high-value measures (§438.330(a)(2)). In the proposed rule, CMS underscores its current authority to require standardized performance measures and explains its plan for engaging stakeholders in a process to lay out required measures for plan performance. We are concerned that federally-established, standard plan performance measures may result in inappropriate and inaccurate comparisons between Medicaid programs and populations. There are fundamental differences between programs and the populations served that necessitate flexibility in the measures on which plans and states report. For example, a single set of measures cannot appropriately examine performance for pregnant women, while at the same time evaluating performance for elderly persons in nursing care facilities. Rather, states are ideally positioned to select plan performance measures that reflect the maturity of their programs and appropriately address quality of care in their risk-based programs. States can also select measures to maximize quality improvement efforts among the participating risk-based entities.

    To better recognize this variation while still achieving CMS' policy goal, we continue to recommend that CMS require plan performance reporting using a menu approach, as we first proposed in our October 2014 letter to CMS in advance of this regulation. Under this approach, states would select a minimum number of measures from a required CMS menu. States could then include state-specific and state-defined measures to further tailor quality reporting to the state's program and population. In developing this menu approach, it will be vital that CMS:

    - **Limit the number of required performance measures.** Historically, CMS measure sets have been large. This restricts states' ability to measure additional items or focus improvement around high value targets due to resource limitations that make it impossible to report on a vast array of measures. Therefore, the required number of performance measures from within the menu should be limited in order to balance the movement toward more standardized measures with the need for states to focus on key areas for quality improvement. We urge CMS to consult with states to ensure the number of required measures is feasible and appropriate.

    - **Ensure the menu of measures contains inclusive and high-value measures.** We encourage CMS to ensure that the measures in the menu are fairly wide and inclusive measures, ensuring that they contain the majority of the population with a condition. In addition, the menu should have process and outcome measures, as well as measures of

both chronic conditions and population health. States believe there is value in looking beyond disease state measures, where possible, and focusing on measures of population health. Once again, states are prepared to support CMS in identifying the most appropriate and effective measures for inclusion in this menu set. It is also important that this approach promote measure alignment and does not result in an unbounded number of measures that are not meaningful.

38. States should be CMS' primary partner in identifying plan performance measures for use in Medicaid, including measures that would be included in a menu approach (§438.330(a)(2)). States have critical experience that should inform the practicality and utility of measure collection and reporting. This consultation needs to occur regardless of whether CMS pursues the recommended menu approach or chooses the less strategic approach of establishing one set of required plan performance measures. To the degree possible, states can help promote relevance to risk-based programs and feasibility in collecting measures. It would also ensure that the list of measures is more balanced and manageable for states and their health plan and provider partners. We stand ready to work with our federal partners, as well as other key stakeholders such as plans and providers, to develop the menu of required plan performance measures for Medicaid.

39. Rather than specifying federally-required performance improvement (PIP) topics, CMS should identify optional PIP topics, which states could elect to use (§438.330(a)(2)). We are concerned that CMS plans to exercise its authority under existing regulations to specify required PIP topics. While some states may find it beneficial to adopt a federally-defined PIP, a CMS mandate for PIP topics could inappropriately constrict and divert quality improvement efforts for other states and runs counter to the intent of a state-defined quality strategy as proposed under this rule. Because of the intensity of PIPs, states often do not require more than a limited number of PIPs at a time. If CMS requires even one PIP topic per year, this could severely limit a state's use of this tool to focus on quality concerns relevant to that state, as well as drive delivery system reform through PIPs. PIPs represent a key tool for states to drive this reform and programmatic innovation, and their utility should not be impeded by the regulation. The proposed approach would also remove the ability to leverage PIPs in other ways. For example, states currently use PIPs to promote plan participation in other multi-agency initiatives, such as a smoking cessation effort or a program for trauma-informed care for foster youth. In addition, states currently use PIPs in a regional manner, requiring different projects based on the region of the state and key concerns in that area.

    Rather than precluding the innovative use of PIPs by specifying PIP topics, CMS should identify high priority topics for PIPs, and offer technical assistance to states and plans around the implementation of these given topics. This will encourage a focus in these areas, but will not force states into efforts that are not aligned with the needs of the program and population it serves.

40. At a minimum, states should be permitted to receive exemptions from federally-identified PIP topics and plan performance measures, as specified in the proposed rule (§438.330(a)(2)(ii)). If CMS decides to disregard our recommendations above and proceeds down the path of requiring a single set of required plan performance measures (as opposed to a menu approach) or specifies required PIP topics, exemptions will be vital to account for basic variations in Medicaid. We agree with the exemptions outlined in the preamble, with some small adjustments, including exemptions:

    - For measures that are not applicable to the population enrolled in the Medicaid managed care program;

    - If the number of enrollees is too small to calculate a measure; and

    - If a plan's performance on a measure has exceeded the 75th percentile for more than 3 years in a row. (We believe that performance in the 90th percentile, as included in the preamble, would not be attainable for even the highest performing plans. The 75th percentile is more appropriate and still reflects high performance on a given measure.)

    We also ask CMS to clarify that similar exemptions would apply to any federally-identified PIP topics, which are not explicitly discussed in the preamble. It is vital that states have the opportunity to receive exemptions from the federal PIP topic due to unique features of their program and high performance in a given area. For example, an exemption would be needed for plans that serve specialty populations (e.g., recipients with HIV/AIDS) that may not have a sufficient number of eligible members for the required federal PIP topic indicators. Finally, we urge CMS to permit states, on an ongoing basis, to put forward justifications for other cases where an exemption from a performance measure or federal PIP topic would be warranted.

41. We applaud CMS for allowing states to use the Medicare Advantage quality improvement project in the place of a Medicaid PIP, but believe this option should apply to plans that serve dually eligible individuals, as well as other Medicaid beneficiaries (§438.330(d)(3)). We are extremely supportive of this flexibility, which gives states an opportunity to align with Medicare in cases where it is appropriate and feasible. This provision would reduce duplication of effort for states, as well as for plans that are serving dually eligible beneficiaries. This option should also reflect that some Medicaid D-SNPs may not exclusively serve dually-eligible individuals. States that have plans that are D-SNPs and also serving other Medicaid beneficiaries should also be able to use a Medicare Advantage quality improvement project in place of a Medicaid PIP.

42. We support the new requirement that plans must have mechanisms to assess quality for enrollees using LTSS (§438.330(b)(5)). States agree that it is important for plans serving those with LTSS to have quality assessment efforts tailored to this population. As more states implement managed care programs for these complex populations, states are dedicated to

ensuring quality improvement efforts take their unique needs into account. We agree that it is important to have plans conduct an assessment when individuals move between settings of care, and conduct a comparison of services received verses services laid out in the treatment plan.

Accreditation or State Review of Plans

43. CMS should maintain the current flexibility for states to determine accreditation requirements for their Medicaid managed care programs (§438.332). We are concerned that the proposed rule creates a de-facto requirement for accreditation, which may not be appropriate in the context of some state programs and plans. The alternative to accreditation, which CMS outlines in the rule, is not a meaningful alternative because states must use the same standards as the accreditation entity. As the rule points out, states would have to purchase standards from one of the accrediting organizations for their own processes.

    This removes the current flexibility states are afforded to ensure that health plans meet the necessary standards to deliver care in Medicaid. The existing approach allows states to require accreditation or conduct a state-defined and state-specific review. It permits states to select and design a review approach that is tailored to the unique populations and risk-based programs they oversee, or states may require accreditation of health plans. A national accreditation requirement, which the proposed rule effectively requires, is a one-size-fits-all approach that would not account for these differences. For example, MLTSS and behavioral health organizations (BHOs) serve unique populations in Medicaid managed care and often cannot meet national accreditation standards due to their specific focus and role.

44. At a minimum, there should be a phase-in period for states to implement the requirement for state review of plans (§438.332). In the event that CMS moves forward with its proposed approach to state review of plans, states should be given adequate time to come into compliance. This would be consistent with the phase-in period that was provided to qualified health plans when accreditation was required in the marketplaces. We urge CMS to consult with states to determine what an appropriate timeframe would be for requiring accreditation of plans or conducting a state review that uses accreditation standards.

External Quality Reviews/External Quality Review Organization

45. CMS should provide enhanced federal financial participation (FFP) for EQRO reviews of all managed care programs, as well as EQRO activities in fee-for-service (FFS) Medicaid (§438.370). CMS's proposal to eliminate enhanced FFP for EQRs performed on PIHPs runs counter to the push to ensure quality under the proposed rule. It also does not align with the expanded requirements that CMS lays out in which EQR activities would apply to PAHPs and, at state option, PCCM entities. CMS' policy goals also appear to conflict with this provision. In many other portions of the regulation, CMS emphasizes its greater focus

on safeguarding quality and promoting value in the program. For example, the numerator of the proposed MLR allows for the inclusion of quality improvement activities, signaling the importance of quality improvement to care delivery. However, in this section, CMS reduces its financial support for external quality reviews and scales back its investment in quality.

Reducing this FFP would not only be a step backward from current policy, it would further exacerbate the lack of parity that exists in federal support for quality review activities today. Safeguarding quality is as vital an activity in FFS and PAHPs as it is in MCOs and PIHPs. Therefore, it is troubling that enhanced FFP is not available for EQRO activities performed for PAHPs and FFS programs. For example, while states receive the enhanced FFP for having their EQRO conduct the Consumer Assessment of Healthcare Providers and Systems (CAHPS) survey in MCOs, this funding is not available when the same organization assesses consumer satisfaction in FFS.

The disparity in funding also has a disproportionate impact on populations that may continue to be served in FFS programs, such as tribal populations. It is inappropriate for CMS to dedicate fewer resources to quality improvement activities for the unique populations that continue to be served in FFS programs.

In order to align with its goals of quality improvement and provide parity in its support for quality safeguards, CMS should build on its original interpretation of the statute and provide enhanced 75 percent match for EQRO providing EQR activities for PIHPs, PAHPs and PCCM entities. CMS should also provide the enhanced match for EQRO activities in FFS programs. The federal investment in these activities shows CMS' commitment to high quality care, and supports states in maximizing the use of EQR activities to drive quality in both their managed care and FFS programs. It also demonstrates the importance of ensuring quality care for the unique populations that continue to be served in FFS programs.

46. CMS should provide enhanced FFP for EQR activities performed by entities other than EQROs (§438.356(a)(2). The rule envisions the use of non-EQROs to conduct some EQR activities, and states believe this is an important flexibility to promote quality in the program (see Recommendation 50). However, the rule does not ensure equal support in federal funding for ERQ activities performed by these other entities; it does not extend the 75 percent FMAP to them. This creates inconsistency in CMS' policy goals and support for quality improvement activities, as discussed above in Recommendation 45.

    This enhanced match would also support states in conducting the variety of new quality requirements under the proposed rule—many of which will increase costs to the state. For example, the new EQR activity to perform network adequacy monitoring, such as secret shopper calls, will be expensive. Federal support for this quality activity, whether conducted by the EQRO or another entity will be necessary to offset this burden.

47. We support state flexibility to use accreditation information in lieu of mandatory EQR activities, but CMS should give states the explicit authority to require accreditation *and* some or all of the EQR activities (§438.350(a)(3) and §438.360). States are pleased that the proposed rule would continue the current policy of allowing accreditation information to be used instead of information gathered from an EQR-related compliance review. We support the option for states to use accreditation to validate PIPs and performance measures. Some states may find it appropriate in the context of their program to leverage this option. Nevertheless, CMS should ensure that states retain the discretion to require the all or certain elements of the EQR, such as site visits. Some states may find value in continuing to require these EQR activities in light of their program and populations.

48. The final regulation should clarify how deeming will occur in light of any CMS-specified performance measures required under this regulation (§438.330(a)(2) and §438.360). The proposed rule expresses CMS' goal of requiring reporting on a set of performance measures. Whether CMS pursues a menu approach, which we recommend, or continues with the ill-advised approach of a single set of measures, we are concerned that there might be misalignment with the option to deem plans that are accredited. The measures accreditation entities use to examine performance might not align with the measures that are required by CMS. We urge CMS to clarify how this lack of alignment would be handled under the deeming option.

49. States should retain the sole authority to determine the methodology for comparative information about plans in the EQR technical report (§438.364(a)(4)). As noted previously, there is significant variation across Medicaid programs, and this variation also exists between plans and programs at the state level. Medicaid has many unique populations that are often served by particular plans and through targeted packages of services and supports. States are in the best position to understand these variations across their managed care program and draw any meaningful comparisons between plans. As such, states should determine the methodologies for plan comparisons that will be included in the EQR technical report.

50. We support the clarification that would permit states to contract with additional, non-EQRO entities to conduct EQR-related activities (§438.356(a)(2)). As states continue to drive innovation in their care delivery systems through managed care vehicles, it is critical that the final regulation accommodate the myriad of state approaches to assessing the quality of their care management entities. Extending the authority to use other entities to conduct EQR-related activities reflects the flexibility states need to tailor their external quality review processes in light of different state program structures and capacity needs. For example, some EQROs will not have the capacity to conduct the network adequacy review activities envisioned under the rule, such as secret shopper calls. In other cases, states may already have other entities conducting this network adequacy review. In this instance, and others like it, it will be important for these states to be able to delegate this EQR activity to other entities.

CONSUMER PROTECTIONS

In this section, we offer comments on a broad array of provisions in the proposed rule that seek to address consumer protections. Some of the issues we raise in this portion of our comments were initially identified for CMS in the Association's September 2014 letter to the agency.

Our comments identify provisions of the rule that would actually harm, rather than protect, consumers and be operationally problematic. In particular, CMS' proposal to require 14 days of FFS coverage while enrollees make an active selection of a plan would threaten quality of care by limiting access to needed care coordination services and the full scope of benefits in managed care. In addition, we raise concerns with CMS' proposal to align Medicaid's appeals and grievances processes with other payers. We point to more effective approaches to shape this process in the Medicaid context.

Finally, we also identify key areas where states support the policy direction in the rule as a way to enhance protections for Medicaid beneficiaries. Specifically, we applaud the proposal to put states at the center of developing specific network adequacy standards, though we request that CMS allow states to use additional metrics of network adequacy to account for unique program and marketplace features.

Our comments are divided into the following sections: enrollment, disenrollment, network standards, beneficiary support system, choice of plans, coordination/continuity of care, availability of services, marketing, grievances and appeals, MLTSS, and information standards.

Enrollment

51. CMS should remove the requirement to provide 14 days of fee-for-service (FFS) coverage while the enrollee chooses a managed care plan (§438.54(c)(2) and §438.54(d)(2)). States share CMS' commitment to ensure that beneficiaries are able to make an informed choice of plans. However, we are deeply concerned that this proposed policy would threaten the quality of care for new beneficiaries while creating major operational issues for states and misalignment with the commercial market. Furthermore, it is an unnecessary complication as consumers already have the benefit of a highly effective protection, which allows them to change plans during the first 90 days of enrollment without cause.

    Medicaid Directors are deeply troubled that the proposed period of FFS coverage would reduce the quality of care for new enrollees by limiting access to care coordination and the full array of services in managed care. Many states structure their enrollment policies to assign an individual to a plan immediately, while allowing the individual to make an informed choice of plans. This approach ensures that new beneficiaries can reap the benefits of care coordination provided by plans upon entering the program. This is particularly important for pregnant women, for whom it is vital to receive coordinated prenatal care as early in the pregnancy as possible. In addition, the proposed 14-day period would prevent

beneficiary access to broader benefits while they are in FFS Medicaid. Many managed care plans offer more expansive benefits than those that are available through the state plan, for example, enhanced outpatient benefits and dental coverage. Many managed care plans also offer an expanded provider network, which the individual would not have access to during the FFS coverage period.

These quality concerns are exacerbated by the fact that a 14-day period in FFS is not operationally feasible, and beneficiaries will be covered under FFS for a much longer period. When coupled with other requirements and timeframes, individuals could be in FFS for a month or more. Take, for example, a state that enrolls individuals in coverage on the first of the month. If an individual is determined eligible on January 19, it could be March 1–six weeks or more–before the individual receives the care coordination and enhanced benefits available through the managed care plan. For a high-risk pregnancy or individuals with complex conditions, this is an unnecessary and potentially harmful delay in accessing care and supports.

The 14-day policy is also problematic because many states have moved away from FFS, as the rule acknowledges. In fact, many states no longer have FFS delivery models in their program. To comply with this requirement, states would have to either create a FFS structure or expand the limited structure that they currently have to accommodate the new enrollment policy. This would have significant resource implications, and would run counter to the movement toward managed care delivery models in Medicaid as a way to drive value in the program.

We are also troubled by the fact that this policy contradicts CMS' stated goal of aligning policies across payers. In the commercial market, including in employer-sponsored insurance, individuals select their plan at enrollment. The proposed policy for Medicaid differs substantially from these other payers by moving away from such timing for plan selection.

During Medicaid's 90 day period of choice, consumers have the opportunity to make an informed decision and can make multiple changes in that time period. The preamble fails to acknowledge that this 90 day period is an added protection that does not exist for qualified health plans on the commercial market, where individuals cannot change plans without cause except at open enrollment.

Medicaid programs take seriously their work to empower consumers to make this choice. States also work diligently to pair individuals with plans that contain their preferred providers and other resources to best meet their needs. These approaches are effective, and states find that it is an *extremely small* portion of individuals change plans once the state has matched them with the plan most likely to meet their needs.

52. We applaud CMS for permitting states to consider additional criteria in the passive and default enrollment processes that would reward high-performing plans (§438.54(c)(7)(ii) and §438.54(d)(7)(ii)). Increasingly, states are using the enrollment process as a tool for driving plan performance. Several states use beneficiary auto-enrollment as an incentive for managed care entities to invest in quality improvement and delivery system reforms. States develop auto-assignment algorithms that use a variety of criteria and are designed to select the best health plan for enrollees who fail to choose their own. We greatly appreciate CMS' recognition of the role of these policies as a tool for states to promote value in Medicaid. This is also an effective practice we highlighted previously in our September 2014 letter on consumer protections in managed care. Further, to promote a climate of innovation, CMS should allow states to propose additional enrollment practices, which may not be outlined in the regulation (e.g., family enrollment preferences, previous plan assignment, other quality assurance and performance criteria, etc.).

53. States should be expressly permitted to suspend passive and default enrollment to a plan as a way to address poor plan performance (§438.54(c)(7)(i) and §438.54(d)(7)(i)). To date, states have used enrollment approaches as one way to address underperforming plans. For example, states may suspend default enrollment in a plan for a period of time until improvement is demonstrated. While we believe the proposed rule would continue to permit these approaches, we ask CMS to explicitly clarify this authority exists in the final rule.

Disenrollment

54. States should have the option to decide if an LTSS provider leaving a plan network should trigger plan choice. And at a minimum, states should not be required to trigger choice if a provider contract is terminated due to quality concerns (§438.56(d)(2)(iv)). We are troubled that the proposed rule would require all states to allow enrollees to disenroll from their plan when a residential, institutional, or employment supports provider exits the network. In many state programs, this new requirement for choice gives providers inappropriate power over LTSS networks and delivery in managed care, and it is also duplicative of existing beneficiary protections. Specifically, it provides a pathway for LTSS providers to withdraw from a MLTSS program due to a preference for fee-for-service, which undermines state efforts to move to value-based care. In many states, this requirement could also result in LTSS providers driving plan participation by choosing to contract with certain plans over others based on the rates that plans are paying.

    Also, under existing regulations, consumers have access to a just cause request to switch plans, including when there is a lack of access to providers experienced with dealing with his/her health care needs. This existing protection recognizes that in many state programs there is generally more than one provider delivering services in the network and allows for an opportunity to change plans if the array of providers is not sufficient. In addition, new network adequacy standards would seek to ensure that consumers have an adequate choice

of LTSS providers. Therefore, it is not necessary to have §438.56(d)(2)(iv) be a requirement, rather, it should be included as a state option.

Further, a provider may be terminated from a plan network for poor quality or other legitimate concerns related to the overall quality and integrity of the plan's LTSS network. At a minimum, CMS should *not* require plan choice to be triggered when a provider contract is terminated due to quality concerns. We are concerned that such a requirement would disincentivize plans from removing poor performing facilities from their network.

55. We support the clarification that individuals receive one 90-day period for disenrollment without cause from the date of their initial enrollment (§438.56(c)(2)(i)). We agree with CMS that the current interpretation of this 90-day choice period, which resets the 90 day clock each time an individual switches plans, is a barrier to enrollee-provider relationships. It also disrupts the ability of plans to coordinate care in an effective manner for beneficiaries. We support CMS' clarification to this policy that would allow one period of 90 days to change plans without cause. This provides sufficient time to allow consumer choice while promoting the establishment of enrollee-provider relationships. We further ask CMS to clarify whether states would have the option to provide a longer "without cause" disenrollment period, which may be appropriate in the context of some state programs and populations.

Network Standards

56. We agree that states should have the primary role in developing network adequacy standards, but urge CMS to allow states to identify the type of network adequacy measures they will use (§438.68(b)(1) and §438.68(b)(2)). States are ideally equipped to understand the dynamics of their health care marketplace and how best to ensure access for the diverse population of beneficiaries they serve and provider types they utilize. As a result, state-specific network adequacy standards ensure that Medicaid Directors can address the key issues in network adequacy, such as how they are securing access in all geographic regions of the state. It also ensures states can safeguard access across plans that serve diverse populations of enrollees. We applaud the approach CMS takes in the proposed rule to put states at the center of the development of these standards.

    Nevertheless, we urge CMS to give states the option to identify the metrics for network adequacy, including the types of measures for LTSS providers. While many Medicaid programs use time and distance standards, other standards may be appropriate in the context of a given provider type and service program. For example, time and distance standards are typically understood in terms of the time spent in a car. This does not account for travel in an urban area, which is likely conducted using public transportation. In these cases, modified time/distance standards, or other standards, may be appropriate. Time and distance standards may also become inadequate as technology evolves and positively impacts how services are delivered.

Flexibility would allow Medicaid Directors to develop more appropriate, flexible, and innovative approaches to network adequacy for these providers. It would also enable states to build on existing standards and effective approaches to measure network adequacy in their programs, and/or use standards that the state may consider to be more rigorous than time and distance requirements.

It is particularly important that states have flexibility around the standards for LTSS providers, including when individuals travel to these providers or when LTSS are provided in the home. Traditional metrics of network adequacy may not be appropriate, such as time and distance standards, due to the nature of LTSS, the geographic composition of accessible providers (especially in rural areas) and the frailty and functional limitations of the LTSS enrolled population. For example, a time/distance approach to network adequacy for LTSS may not be possible if states do not directly enroll attendant care providers. In another instance, adult day care services may not be available in all areas of a state, and the state may rely on in-home companion, personal care, and respite care to fill any gaps. Time and distances cannot recognize this type of nuance in LTSS. Therefore, states should have the flexibility to develop innovative standards or indicators of insufficient provider networks (see Recommendation 60).

57. CMS should not require specialty providers to be a standalone category for network adequacy purposes and states should retain the authority to identify any other provider types that would need to meet network standards (§438.68(b)(1)). There is a very broad spectrum of providers included under the term "specialty," which makes it problematic to include this as a standalone category for network adequacy purposes. This category could encompass providers ranging from more common specialists, such as cardiologists, to very rare subspecialists, such as pediatric neurologists. In some cases, there may only be one or two subspecialty providers in a given state, if there are any at all. Therefore, it is not feasible or appropriate to apply one set of standards to a class of providers with such diverse features and differing availability.

    States already have approaches in place to ensure access to these highly specialized providers, which the final rule should recognize. Medicaid programs regularly conduct single case agreements with highly specialized providers. These agreements ensure that Medicaid programs and plans can reach beyond their health care marketplace to provide the full range of specialty care.

    In addition, states should have the flexibility to determine what additional provider types should meet the state's network adequacy standards. We believe the requirement to establish time and distance standards for additional provider types, as determined by CMS, is too broad. In addition, as we note in Recommendation 56, states should be able to use other standards besides time and distance.

58. We applaud the option for states to apply varying standards for the same provider type based on geographic area (§438.68(b)(3)). Medicaid Directors are acutely aware of the differences that exist in the health care landscape across a state. This includes many unique challenges that are present in rural regions of states. The ability to adjust network adequacy standards for geographic differences allows states to shape these standards in the context of their provider landscape and appropriately measure access in their program.

59. CMS should provide a phase-in for new network adequacy standards (§438.68(b)). If CMS proceeds with requiring time and distance standards, it will take states that do not currently use such standards time and resources to develop them. States will have to conduct in-depth analyses and potentially obtain outside support and expertise to do this. They may also have to obtain new software to conduct these analyses. Likewise, plans will need time to come into compliance with any new requirements, including modifying their networks. Therefore, we urge CMS to provide either 24 months following the effective date of the final rule or the beginning of the next contract period–whichever is later–for states to finalize their network adequacy standards and to incorporate these into contracts.

60. CMS should not define the specific time and distance or provider-to-enrollee ratio standards per provider type (§438.68(b)(1)). It is vital that CMS not apply more prescriptive national network adequacy standards in Medicaid due to the complex and varied needs of Medicaid enrollees, as well as the variation and nuances in state health care marketplaces. Medicaid managed care programs are designed to improve access and better coordinate and manage services for enrollees with a broad range of medical, behavioral and supportive service needs. States may offer plans for those with behavioral health conditions, children with special health care needs, or for long-term services and supports for older people and people with disabilities. Prescriptive federal network adequacy standards for managed care would not capture the critical differences within a state's managed care programs, which are necessary to meet the complex and varied needs of Medicaid enrollees.

    Furthermore, federal time and distance standards could not sufficiently account for the differences between state health care marketplaces, including the unique geographic challenges that are present in many rural regions of states. This is demonstrated by the fact that existing federal network adequacy approaches, such as in Medicare Advantage, are not appropriate for Medicaid managed care networks. Applying federal standards would result in perverse incentives that drive up the cost of services simply to meet the standards, as well as potentially undermine existing state initiatives aimed at orienting their delivery systems toward high value providers.

    These federal standards also could not account for the unique nature of LTSS. For example, many states offer participant-directed care, and the enrollee often chooses a friend or family member to provide attendant care services. States and MCOs that offer participant direction may not have a pool of providers to evaluate for network adequacy in light of one-size-fits-all federal standards. As such, network adequacy standards for LTSS services must be

designed in the context of the state program to account for the unique features its LTSS benefit.

61. We agree that states should have the option to exempt a plan from its network standards and ask CMS to clarify how states would consider access in the broader community as the basis for such exceptions (§438.68(d)). As we note above, the differences between state health care marketplaces and provider landscapes are significant, including the unique geographic challenges that are present in many rural regions of states. One set of standards may not be able to account for all of these nuances, making an exception process vital. Medicaid Directors appreciate CMS' recognition of this fact, and for allowing exceptions to be specified in the contract and to be based on the number of health care professionals in that specialty practicing in a given service area. To ensure that states can comply with the exception process, we also ask that CMS provide further clarity around the use of this community access standard when considering exceptions.

62. States should not be required to certify provider networks annually (§438.207(c)(2)). While it is reasonable for states to certify provider networks when the plan enters a contract with the state or when there are significant changes (as defined by the state), an annual certification requirement is duplicative and places a major administrative burden on states. In §438.358(b)(4), CMS includes a new mandatory EQR activity that would require the validation of network adequacy of MCOs, PIHPs, and PAHPs during the preceding 12 months. With this annual EQR activity in place, it is unnecessary to require states to annually certify the adequacy of provider networks. As such, this separate annual certification requirement would create an unnecessary administrative burden on states, without any benefit to quality or plan performance.

Beneficiary Support System

63. CMS should not require the development of a beneficiary support system, but should outline principles of consumer engagement (§438.71). Medicaid Directors share CMS' belief that informed member choice is an important component of the enrollment process and that consumers should be educated about their coverage. However, CMS' proposed approach to the beneficiary support system undermines the effective and state-tailored systems that are in place to engage beneficiaries in enrolling and understanding their coverage.

    A prescriptive CMS approach to beneficiary engagement fails to recognize critical differences between states, including what entities are best positioned to reach different subsets of enrollees. For instance, a state may be working with one entity to support plan choice for pregnant women and children, as compared to a separate entity that is trusted source of information and support for those with disabilities. In particular, the needs of enrollees in LTSS can be so highly specialized and individualized from beneficiary to beneficiary that the task of properly educating consumers about plan features may be too

nuanced for a single education entity to accomplish. Directors' experiences with MLTSS and Duals Demonstration Projects show this often to be the case.

Therefore, we urge CMS to lay out key principles of consumer engagement rather than requiring the proposed system. These principles would ensure that CMS' goals around consumer engagement are achieved, while promoting the effective aspects of existing systems and tailored approaches. Medicaid Directors are prepared to partner with CMS, consumers, and other stakeholders in developing the principles that would further enhance states' existing consumer engagement work.

64. At a minimum, states should decide what entities and individuals may provide choice counseling and be permitted to determine conflict of interest safeguards (§438.71(c)). If CMS proceeds down the ill-advised path of requiring a single approach to beneficiary support systems, it is important that states decide who provides choice counseling and the standards they must meet to protect against conflicts of interest. Different entities and individuals will be positioned to provide choice counseling to enrollees across Medicaid programs, which only a state can adequately assess. For instance, there will be cultural and demographic differences in populations that will require partnership with different entities. States should also determine the conflict of interest safeguards that will apply, including firewall approaches they may wish to employ. This will help states align with existing insurance law for brokers around conflict of interest, if applicable, as well as ensure there is an appropriate pool of individuals with the expertise to carry out this function.

Choice of Plans

65. We support the new definition of rural areas for the purpose of allowing an exemption of plan choice (§438.52(b)(3)). States have long been concerned that the current approach for defining rural areas, which uses metropolitan statistical areas (MSAs), is flawed. This is an issue NAMD raised in our September 2014 letter to CMS on consumer protections in Medicaid managed care. In some regions classified as an MSA, the population density is extremely low and the population cannot support multiple health plans. We are pleased that CMS is proposing a new approach to defining rural areas for the purpose of determining those regions that do not have to provide plan choice. We believe the new approach, which would use Medicare's county-based classifications to set network adequacy standards, would remedy states' longstanding concerns. We agree that it should consider any county with a designation other than large metro or metro as a rural area for purposes of the Medicaid plan choice requirement. Some states may still continue to need a waiver for plans that may be serving a very limited number of members but the proposed Medicare designation is a significant improvement.

66. CMS should not require plan choice for PIHPs and PAHPs (§438.52(a)). We are concerned that the requirement to provide plan choice for PIHPs and PAHPs does not recognize the unique features of these plans. As organizations, PIHPs and PAHPs are typically limited in

their scope, providing only a few services to certain enrollees, such as dental services to children. Their scope may also be limited by only providing services to a select population, such as enrollees who are out-of-state for a period of time. Because of their unique role and limited scope, it would be inappropriate to require plan choice and may impact the utility of this model to deliver services to Medicaid beneficiaries.

Coordination/Continuity of Care

67. Transition of care requirements should be determined by the state in its contracts with health plans, and not federally established or structured (§438.62(b)). Directors support the goal of the proposed policy to support continuity of care when individuals move from FFS into managed care or between MCOs. These policies, however, are most appropriately determined by the state. This is because transitions of care is a dynamic and complex policy issue and the state–plan relationship provides the best vehicle for establishing effective transition policies that ensure continuity of care. At the state level, transition approaches can be tailored to enrollees and their needs at a granular level. In fact, many states work directly with their plans on a case-by-case basis, and have tailored their policies to the needs of various populations. CMS should support states in this area by facilitating state-to-state networking on effective transition of care policies that states may apply to their risk-based entities, rather than set a federal standard.

68. CMS should recognize limitations on the requirement to share enrollee health records due to 42 CFR Part 2 (§438.208(b)(5)). We support the requirement that all providers, practitioners and suppliers maintain and share an enrollee health record; however, there are also limitations on sharing the entire health record due to federal restrictions on substance use disorder data sharing. Under 42 CFR Part 2, enrollees must give consent each time their substance use disorder treatment information is shared. This standard is much more burdensome than HIPAA requirements and may preclude providers from exchanging this portion of the enrollee health record. Medicaid Directors have long been concerned that this regulation on substance use disorder data is a barrier to effective care coordination. Therefore, we continue to ask CMS to address this barrier, and at a minimum, reflect this limitation to data sharing in the final regulation.

Medical Necessity

69. CMS should remove the reference to EPSDT as part of the definition of medical necessity to safeguard against unintended consequences, including an unbounded application of EPSDT (§438.210(a)(5)(ii)). CMS' proposal to modify the definition of "medical necessity" could have significant unintended consequences on the application of EPSDT in Medicaid. Section 438.210(a)(5)(ii), read together with the text of the preamble, appears to countermand existing guidance and legal opinion that a state may limit EPSDT services based on its definition of medical necessity (see State Medicaid Manual and the Eleventh Circuit Court of Appeals' decision in Moore v. Reese, 637 F.3d 1220 (2011)). Instead, the rule defines

medical necessity based on EPSDT, which could inappropriately be interpreted to require states to revise their current definition of medical necessity and would likely result in litigation. We are further concerned that including EPSDT in the definition of medical necessity could be read to apply to unintended populations under EPSDT, such as adults, thereby provoking additional litigation.

Availability of Services

70. States should continue to determine the approaches to evaluate if plans are meeting timely access standards. The preamble notes that CMS is considering a variety of mechanisms for states to measure timely access. While Medicaid Directors share CMS' goal of ensuring sufficient access to care for Medicaid beneficiaries, it is important that states retain the authority to set appropriate access standards in light of their risk-based contracts and populations served. It is also important that states shape their access standards in the context of access that exists for the general public outside of Medicaid. States are best positioned to identify such standards and ensure they are applied in a way that is meaningful and effective.

71. CMS should clarify that the Medicaid agency is not responsible for determining provider compliance with statutory requirements that exist and are enforced outside of Medicaid (§438.3(f) and §438.224). We fully support the objective of ensuring that services are provided in a non-discriminatory fashion and acknowledge that Medicaid programs have certain obligations in that regard. However, we are requesting clarification of the scope of that obligation. Section 438.3(f) would require managed care contracts comply with applicable state and federal anti-discrimination laws. Without clarification, this provision might be interpreted to impose an obligation on the Medicaid agency to investigate and make findings regarding complaints arising from discriminatory conduct. State Medicaid agencies have neither the expertise nor the legal authority to conduct formal investigations or make such findings that are assigned by law to other state and federal agencies. Rather, Medicaid agencies should be expected to make appropriate referrals to those agencies or to take appropriate contract action with respect to managed care entities that engage in a pattern of non-compliance.

    We request that similar clarification be made to §438.224, which requires states "ensure through contract" that managed care entities comply with the federal health information privacy requirements. CMS should specify that the state Medicaid agency is expected to make appropriate referrals and take contract action for patterns of non-compliance, but is not obligated to conduct formal investigation and/or to make findings regarding potential privacy violations.

Marketing

72. We applaud the modernized approach to marketing materials that would permit the use of electronic communications (§438.104(a)). CMS' proposal to include electronic communications, including email, social media and text messages, is a welcome approach. This change aligns with previous recommendations NAMD offered in our September 2014 letter to CMS, which requested flexibility for states and plans to communicate with beneficiaries in the manner the beneficiary prefers, as well as our recommendation that CMS' rules be "evergreen" to encompass future technological developments. We believe CMS' proposed definition of marketing materials reflects these recommendations and are supportive of this proposal.

Grievances and Appeals

73. CMS should permit states greater flexibility in establishing their grievance and appeals processes to ensure the highest level of consumer protections (§438.402, §438.406 and §438.408). We are troubled that this rule would over-standardize grievance and appeals, and make it difficult for states to protect consumers through a variety of efficient and effective processes. In fact, the single structure laid out in the regulation could actually limit consumer protections in place today. CMS should instead review and approve state grievance and appeal frameworks, and provide states with significant flexibility in this area to lay out an approach that reflects community expectations, existing state laws, and sound practices in consumer protection.

    We urge CMS to revisit this framework provide state flexibility. If this is not possible, we encourage CMS to consider, at a minimum, the following recommendations in this area (see Recommendations 74-78 below).

74. CMS should set a time limit for plans to complete their appeal processes, rather than limiting the tools at plans' disposal (§438.402(b)). Medicaid Directors are dedicated to ensuring that the appeals process is effective at addressing beneficiary concerns and at operating in an efficient and seamless manner. Because of this, it would be more appropriate to establish a time limit for plans to conduct their internal appeal processes. This incentivizes plans to resolve consumer concerns efficiently, rather than setting restrictions on the internal tools to resolve an appeal.

75. The appeals process should allow for the use of an external review, at the beneficiaries' option (§438.402). Some states have additional mechanisms in place for enrollees to resolve appeals outside of the internal plan appeal and state fair hearings process. These external review processes are highly effective at resolving consumer concerns, and would lessen the potential burden on the state fair hearing process. CMS should permit states to maintain or implement these alternative arrangements, which could be provided at the option of the

beneficiary in the appeals process.

76. States should retain the flexibility to require beneficiaries to initiate appeals within 30 and 90 days (§438.402(c)(2)). We are concerned that the proposed 60 day timeframe for beneficiaries to initiate an appeal of adverse benefit determinations will create major operational concerns at the plan and state level. CMS proposes that an appeal may be initiated up to 60 days after an adverse benefit determination. However, current policy allows states to set the timeframe for appeal between 30 and 90 days. Many states use this existing flexibility to set their appeal timelines below the proposed 60 days. They do this because the 60 day requirement creates a significant retroactive liability period for plans in the event of an appeal being upheld. This is particularly problematic considering that the state fair hearings process may take an additional 60 days or more. Also, in the event that beneficiaries are held liable for services delivered during the appeal, this timing could create major financial obligations for individuals as well.

77. CMS should give states the option to exclude administrative denials of payment as a criteria for a state fair hearing (§438.400(b)). It is important that CMS clarify the inclusion of "denial of payment" in the definition of an adverse benefit determination. Denial of payment for a service for administrative reasons, such as late filing, lack of prior authorization, etc., will not impact beneficiaries in states where providers cannot bill a beneficiary if a claim is denied. At the same time, the managed care entity and the provider share a contract that details administrative conditions for proper payment. These denials may not be appropriately addressed through a fair hearing, could inundate the fair hearing process, and place states in the midst of plan-provider disputes.

78. Providers should only be permitted to file an appeal on behalf of enrollees if they have express written consent of the individual (§438.402(c)(1)(ii)). The right to appeal an adverse benefit determination fundamentally lies with the enrollee. While an enrollee may find it appropriate to seek assistance from their providers in initiating an appeal, enrollees should provide written consent and be aware of the steps the provider is taking on the enrollee's behalf. Without this safeguard, there is potential for providers to initiate appeals without an enrollee's knowledge and which may not be in an enrollee's interest.

79. If CMS requires a 72 hour timeline for expedited appeals, a transition period should be provided for plans to come into compliance (§438.408(b)(3)). CMS proposes to require Medicaid managed care plans to resolve expedited appeals within 72 hours of their receipt, rather than the current policy of 3 working days. While plans with lines of business in other markets may be equipped to resolve expedited appeals in in this timeframe, smaller community plans that exclusively serve Medicaid beneficiaries will need considerable time to come into compliance with this requirement. We request that CMS provide a phase-in period if CMS finalizes this requirement.

MLTSS

80. CMS should not require LTSS services authorized through an HCBS authority to comply with the HCBS settings final rule until 2019 (§438.3(o)). We are concerned that the proposed rule would require any LTSS benefits, which could be authorized under an HCBS authority, to be delivered in settings compliant with CMS' HCBS final rule. Many states are currently still assessing their HCBS settings for compliance with this rule, and it is unclear how these settings assessments will impact the overall availability of HCBS providers and settings in MLTSS programs. The timeline for states to bring their settings into compliance with the HCBS rule is in 2019. The requirement that MLTSS benefits be delivered in HCBS-compliant settings takes effect beginning with the rule's effective date, likely in 2016, under this proposed rule. CMS should revisit these timelines and align any requirements around the HCBS settings across both regulations.

81. We urge CMS to restrain from providing a federal definition of LTSS for purposes of this regulation (§438.2). States are concerned that the any federal definition of LTSS may not reflect the true scope of LTSS, especially in risk-based programs. The proposed definition appears to be expansive and could inappropriately apply the provisions of the rule around long-term care services to certain intermediate rehabilitation services. We believe it is more appropriate for states to set a definition of these services in the context of their program and risk-based models. If this is not possible, CMS should revisit and narrow the scope of the definition.

    At a minimum, the agency should also only apply the definition for purposes of this regulation. Applying the definition outside of this regulation would have unintended consequences on many other elements of the Medicaid program, including on the appropriate application of parity requirements.

82. States should have the flexibility to determine what LTSS providers must be credentialed (§438.214(b)(1)). It is operationally unfeasible for CMS to require credentialing for all LTSS provides in Medicaid. For example, many in-home providers of LTSS services are family members who are delivering care. It would create an undue burden on these individuals, the state, and plans to require all of these individuals to undergo a credentialing process. The proposed requirement would also undermine the ability of the state and plans to leverage a range of new innovative provider types, which are likely to continue to emerge as states enhance their LTSS programs.

    At a minimum, CMS should clarify that the term "uniform" in this context does not require one set of credentialing requirements to apply across provider types. States want to ensure that they can hold varying provider types to different credentialing requirements based on their scope of practice and professional standards. For example, LTSS providers, such as family caregivers, and primary care providers should not have to meet the same

credentialing standards.

Information Standards

83. We applaud the flexibility for states and plans to provide information to enrollees using electronic formats (§438.10(c)(6), §438.10(e)(1) and §438.10(h)(1)). The technological environment in which modern health services operate has changed substantially since CMS promulgated its initial Medicaid managed care regulations. Because of this, we appreciate CMS' acknowledgement that electronic communications play a major role in modern program management. The option to provide information in an electronic or paper format will support states in communicating with beneficiaries in the methods the beneficiary prefers. It will also ease the burden on states and plans associated with providing hard copy materials to consumers who regularly use electronic communications. In particular, we appreciate the option for provider directories to be made available in paper or electronic format as part of member choice packets.

84. We strongly support the option for states to host a link to plans' websites, as an alternative to hosting enrollee handbooks and provider directories on the state's website (§438.10(c)(3)). Plan provider networks change and plans are required to update their provider directory on a regular, frequent basis. As such, there would be many operational challenges associated with maintaining the updated directories and handbooks on states' individual websites. Further, the responsibility for hosting the documents lies first with the plan. Therefore, we strongly support the flexibility for states to link to individual plan websites rather than directly to online plan enrollee handbooks and provider directories.

PROGRAM INTEGRITY

Medicaid Directors take their responsibility for maintaining the integrity of the Medicaid program very seriously, and are committed to working with CMS to identify approaches to reduce fraud, waste and abuse in risk-based programs. In our recommendations, we identify a number of opportunities for CMS to better support states in improving program integrity. In particular, we urge CMS to permit a variety of centralized enrollment approaches to better reflect the range of enrollment models that achieve the goal of the regulation. We also ask CMS to support states in enhancing their encounter data, rather than removing federal funding while states are working to tackle the complex challenges in this area. Finally, we focus on areas where CMS could provide states with more explicit authority to outline program integrity requirements in their risk-based programs.

Our comments are divided into the following sections: provider enrollment/plan exclusion status, sub-contractual relationships, data and reporting, state program integrity and compliance programs, recoveries, sanctions, deferral and/or disallowance of FFP, state monitoring standards, and third party liability.

Provider Enrollment/Plan Exclusion Status

85. CMS should clarify that states may pursue a variety of provider enrollment approaches rather than only requiring one approach (§438.602(b)). Medicaid Directors support the policy direction to promote models of centralized, coordinated provider enrollment, which states find effective to strengthen their program integrity initiatives. The proposed single approach for centralized enrollment, however, rejects the use of other coordinated provider enrollment methods to drive program integrity. States that currently use these other enrollment approaches have adapted these models to effectively support program integrity in the context of their unique program structure, provider landscape, and key challenges. For example, some states require network providers to be enrolled in FFS Medicaid, but the responsibility for enrollment and related activities lies with the plans. In other cases, states have mechanisms in place to identify providers in the plan's network and can discontinue the participation of a provider, if necessary. These approaches, and others like them, achieve the goals CMS intends while accounting for variation.

    In addition, CMS' proposed approach would be costly for states and difficult to implement. States will need to dedicate significant resources to build, test and implement an enrollment tool to accept and process the data files that states would be receiving from plans. Further, the proposed approach could also impact the time it takes for a provider to enroll in a plan, thereby raising access concerns and creating provider frustration.

    In the event that CMS does not permit a variety of approaches, as we suggest above, we ask for clarification that states could delegate to plans or other entities many or all the activities under §438.602(b). States should have the option to work with other entities to conduct these activities to the greatest degree possible, which would promote flexibility and align with a broader range of state centralized enrollment structures.

86. CMS should streamline the mechanisms and tools for states to comply with federal provider screening and enrollment requirements, as well as newly proposed checks on plans' exclusion status (§438.602(d)) . We are troubled that the proposed rule does not address states' longstanding concern with the disparate federal databases and processes that states use to comply with provider screening and enrollment requirements. States must use many different federal databases for provider screening, each with variable requirements and processes. These include the List of Excluded Individuals and Entities (LEIE), Provider Enrollment, Chain and Ownership System (PECOS), Excluded Parties List Search (EPLS), Termination Process, etc. In addition, changes to provider enrollment under the Affordable Care Act have increased the complexity of the screening process, including requiring site visits for providers classified as high-risk.

    This problem will be made worse by the CMS proposal to require monthly database checks on the exclusion status of health plans and their subcontractors. This exacerbates the longstanding challenges with federal database checks for Medicaid providers. Before CMS

requires monthly database checks on plans and their subcontractors, CMS must streamline the process for states to check these databases.

CMS could streamline provider and plan checks through a couple of approaches, which move towards batch matching and other simplified processes:

- To support provider enrollment processes, CMS could use the disclosure requirements as the base document and add in the other necessary relevant requirements to streamline the enrollment process. CMS, with input from states, could establish the minimum required information while allowing states to insert additional, state-specific fields. This would allow CMS to conduct the necessary checks at the federal level while still proving some baseline standardization among states.

- To further support provider enrollment and to regularly determine the exclusion status of plans, CMS could establish a single portal where states can access downloadable, real-time information contained in the aforementioned databases. States appreciate that CMS has been working to develop a portal (OnePI) to meet this objective, and we urge CMS to prioritize this portal activity. CMS could also explore making existing data sources available to states to achieve the same goal. For example, the U.S. Treasury's "Do-Not-Pay" database aggregates all or most of the information that states would need to comply with federal screening requirements. We also encourage CMS to examine the feasibility of establishing a database that could provide information regarding previous civil or criminal action by other states or the federal government against managed care entities and/or the principals of those organizations.

87. <u>CMS should assist states in developing streamlined enrollment processes for highly specialized providers.</u> While rare, there are instances where the complex health care needs of Medicaid enrollees require the expertise of unique providers, such as subspecialists and specialized children's hospitals. In many instances, these specialized providers reside and have completed the screening, background check and disclosure requirements in their home state's Medicaid program or the Medicare program. States and their Medicaid beneficiaries would benefit from CMS guidelines related to expedited enrollment of highly specialized providers; the process would not apply to regular provider enrollment and credentialing processes.

    In the final rule, CMS should clarify that states may rely in part or entirely on the provider's home-state Medicaid background check results and disclosures or those for Medicare, including for fingerprint-based background checks. This would be limited to certain providers that are identified by the non-home state. A regional or centralized, standard process for specialized providers already screened by and enrolled in a state Medicaid program or Medicare would significantly minimize the burden on providers. In turn, this

would help to facilitate access to critical services in a timely fashion for enrollees.

88. CMS should not apply the prohibition on payments to entities outside of the U.S. to subcontracts for administrative services that do not touch members directly (§438.602(i)). We are concerned about the impact of the proposed requirement that no claims paid by an MCO to a subcontractor located outside the U.S. could be considered in the development of actuarially sound rates. This could inappropriately limit the ability of plans to subcontract for certain administrative functions, such as IT or other operational services. CMS should limit the regulatory language of "provided under the State plan" to reflect only medical services and not to administrative services that do not touch members directly.

Sub-contractual Relationships

89. States applaud the new requirements that promote program integrity across subcontracted entities (§438.230). States recognize the importance of ensuring that both contracted entities, and those entities which are delegated functions and responsibilities, are in compliance with program requirements. As such, we appreciate the new protections that would help states promote integrity across any subcontractors. We agree with CMS that it is important for the plan to be accountable for compliance of all entities and to hold subcontractors to the same program standards under the contract. We also appreciate the recognition that states should be able to provide appropriate oversight of these entities, including any necessary audits.

Data and Reporting

90. We support the requirement that plans and PCCMs/PCCM entities must submit data to the state and attest to its review, which are an important first step for states to safeguard program integrity (§438.604(a), §438.604(b), §438.606, and §432.242). A fundamental principle of managed care is that states must know who is receiving payment for which services on behalf of a specific recipient. It is also key for states to have data on recoveries and overpayment, as well as other performance obligations. Reliable and accurate data are foundational to ensuring program integrity in managed care. Therefore, we appreciate that plans would be required to transfer reliable and accurate data in a timely fashion. We also appreciate that plans would have to conduct proactive compliance reviews.

    As CMS finalizes these requirements, it is important these requirements are understood to be the floor for state and plan collaboration around program integrity. Submitting high quality encounter data and attesting to its accuracy is the first and most important step in a plan's responsibility to support program integrity efforts. States will need to continue to work with plans to assure high quality data and engage plans in their efforts to promote program integrity across Medicaid.

91. Encounter data requirements must be aligned with transformed MSIS (TMSIS) and other federal expectations for data reporting (§438.604(a) and §438.604(b)). Prior to the release of

the rule, CMS has been enhancing its reporting requirements and expectations of states around encounter data. In these efforts, we have found that CMS' standards and expectations are not aligned across the various Medicaid transactions that occur. Specifically, TMSIS submissions are inconsistent with the type of data that CMS has been seeking through standard encounters and claims reporting structures and other transactions that impact program integrity initiatives. This makes it difficult for states to align their own reporting requirements for risk-bearing entities and subsequently to provide CMS with the information it seeks. Therefore, we urge CMS to ensure that all encounter data reporting requirements under the final regulation are aligned with the expectations for TMSIS and other relevant CMS reporting requirements for this data.

92. The data certification and review process should not obstruct the regular transmission of data (§438.606). We agree that a plan's executive leadership should directly attest to its reasonably diligent review of the data, documentation and information it submits. As CMS suggests in the proposed rule, this is a fundamental responsibility of plans and the quality of the data should be assured directly by the plan leadership. Nevertheless, it is important to ensure this requirement does not impede the regular and efficient transmission of data, which enhances program integrity efforts. In some cases, states have processes in place to receive data on a daily basis. This may not be possible if the CEO/CFO has to certify the data concurrently with its submission. The final rule should revise this approach to allow data to be certified in a manner that permits frequent data transmissions.

93. Regular correspondence between health plan staff and the Medicaid agency should not be treated as information that needs to be certified (§438.604(b) and §438.606(a)). The proposed rule appears to require any information related to the performance of the entity's obligations to be certified by the CEO or CFO. If this requires all or most communication regarding the entity's functions to come from the CEO and CFO, this could have implications for the day-to-day correspondence between the entity staff and Medicaid agency staff. For example, it could preclude a plan's information technology team from emailing with the state Medicaid agency to discuss system issues or other technical details. Consequently, this would make it difficult for the Medicaid agency to work with plans to carry out regular activities. To address this concern, CMS should explicitly permit regular communication between the entity's staff and the state to occur without the need for certification.

94. Requiring plans to report detailed changes in enrollee and provider circumstances (other than reporting of TPL) would create an unnecessary administrative burden with limited program integrity utility (§438.608(a)(3) and §438.608(a)(4)). While we support the intent of this proposed policy, we believe these requirements have limited utility for states to promote program integrity and would place a major administrative burden on states and plans. Specifically, there would be little or no utility in having MCOs report enrollee changes. For example, returned mail cannot the sole basis for action around eligibility or enrollment. It is also unclear what states would be expected to do with this and other

information. Another example is changes in income. States do not anticipate that MCOs will receive accurate or reliable information regarding enrollee income.

Another operational issue is that the Medicaid agency may not be the system of record for reported changes, especially if the system is not the MMIS, and therefore could not act on the information. This would make it challenging for states to use the information that it receives from plans. In this case, states would need policy change to be able to update another system of record for this provision would have any value.

Likewise, these plan reporting requirements would duplicate existing mechanisms in Medicaid to capture beneficiary and provider changes in circumstance. For instance, the public health department is already identifying relevant changes in provider situations in many states. We recommend that CMS not overburden states with this volume of information which will not prove operationally useful.

The one area where plan reporting of beneficiary changes would support program integrity is around TPL. It is reasonable to require plans to report any TPL they become aware of, if that source of TPL is not already known to the state.

95. We agree that plans should report potential fraud and improper payments, but urge CMS to give states the explicit authority to articulate additional expectations for reporting, including defining improper payments (§438.608(a)(2)). Medicaid Directors are working with their plans to identify and reduce fraud, waste and abuse in the program. Directors seek to ensure there are clear expectations for reporting and support plans in understanding the differences between potential fraud and improper payments. Many states are also developing pathways for plans to communicate potential overpayments early in the process, prior to plan initiation of overpayment recoupment. This enables states to provide oversight of these efforts.

    Therefore, CMS should also give states the option to articulate additional requirements for identifying and reporting on fraud and improper payments, in addition to the reporting required under the regulation. For example, states may wish to define the scope of the entity's data mining activities within its Medicaid line of business and how such activities are integrated with other functions within the plan, such as medical management, provider services and claims pre-payment reviews and adjudication. States should also be permitted, but not required, to define improper payments in the context of state program integrity efforts. These definitions can be useful to establish a common understanding of the differences between overpayment and fraud, which in turn can promote appropriate reporting.

96. CMS should not withhold FFP for incomplete encounter data, but should collaborate with states in understanding and addressing key challenges in collecting and reporting encounter data (§438.818). States are committed to ensuring timely, accurate, and complete encounter

data and are partnering with CMS, plans and other stakeholders to address the complex issues around encounter data. States are dedicating new and enhanced resources to this work. Because of this, we are troubled by the proposal to withhold FFP for non-compliant encounter data, which would strip states of the resources to tackle the challenges in this area. A more effective and appropriate approach would be for CMS to partner with states to understand and help address the inherent challenges in obtaining and reporting compliant, high quality encounter data.

We are also concerned that the approach for operationalizing this policy is unclear in the NPRM. For instance, the rule does not specify whether states would receive full FFP once corrected data is accepted by CMS or if FFP would be disallowed completely. It is also unclear whether FFP would be withheld for all data deemed non-compliant or if states could achieve a reasonable threshold for the quality of encounter data and receive full FFP. These outstanding questions only underscore that collaboration with states is a more appropriate pathway to address encounter data challenges.

97. If CMS chooses to disregard our recommendation above, they should at least clarify that the withhold would only be linked to the quality of encounter data and not to requirements for MSIS (§438.818). Under the proposed rule, CMS appears to condition FFP for encounter data both on the requirements for MSIS, as well as the quality of encounter data itself. This is problematic and inappropriate in the construct of state approaches to data validation, which may use separate processes for mapping MSIS submissions and encounter data. Specifically, states' submission of data files to MSIS may be impacted by the receiving MSIS system as well as the changing nature of the MSIS data dictionary and file format. While submission to MSIS is an important part of the federal regulatory framework, it is difficult to associate MSIS compliance with the accuracy and completeness of state encounter data.

98. The timeframe for states to develop a detailed plan for meeting CMS requirements for encounter data should provide more than 90 days and reflect states' unique situations (§438.818(d)). The proposed encounter data and corresponding process requirements reflect varying degrees of policy shift in states. States will need to conduct different levels of systems analysis to ensure submitted encounter data meets CMS expectations. Further, many states may need to make changes to their contracts to come into compliance, which will require CMS review and approval. These changes will require much longer than 90 days. Therefore, we encourage CMS to provide more than 90 days for states to meet these requirements, especially if the new requirements represent a larger-scale shift. And at a minimum, states should be permitted to seek an extension for meeting the new requirements around encounter data collection and validation processes.

99. CMS should revise its approach to the information that states must make publically available, laying out a more rational and appropriate scope of information (§438.602(g)). The proposed rule would require states to make publically available an array of information that should be kept confidential for business and consumer privacy reasons. For instance, the

proposed rule would require states to release managed care contracts, which contain the rates that health plans are paid. In many states, this information is considered to be proprietary, and releasing this threatens the ability of states to competitively contract with plans.

We are more perplexed and troubled by the requirement for states to report all of the data submitted under §438.604. This includes encounter data and other data submitted by the plan to the state, which the proposed rule does not require to be de-identified. This conflicts with the protections for health information under the Health Insurance Portability and Accountability Act. We also strongly discourage requiring the posting of this information de-identified, as the burden of de-identifying the data coupled with the continued privacy risk to individuals would not be acceptable, nor would there be any utility in making such de-identified data available to the general public.

In addition, the reporting requirements would not create meaningful transparency for the public and would result in an administrative burden for the state. Providing the public with an insurmountable quantity of information keeps individuals from accessing the most pertinent and useful information. It would require stakeholders and consumers to sort through irrelevant documents, data and other information to identify the information they may be seeking. In order to achieve transparency that is both appropriate and meaningful, CMS should revise this section of the regulation to more specifically target only that data that is necessary and useful to the goals of this section. CMS should also consult with states to identify what information would promote transparency and be rational for the program to report.

State Program Integrity and Compliance Programs

100. States should be permitted to establish additional standards for compliance staffing for risk-bearing entities in addition to the staffing requirements in the NPRM (§438.608(a)(1)(ii), §438.608(a)(1)(iii), §438.608(a)(1)(iv), and §438.608(a)(1)(vii)). We appreciate CMS' recognition of the need for risk-bearing entities to have staff dedicated to compliance, including staff to conduct internal monitoring and to investigate and correct these concerns. We noted the utility of such requirements in our September 2014 letter to CMS on program integrity and are pleased to see our recommendations reflected in the proposed rule. While Medicaid Directors agree with the proposed staffing requirements, we believe CMS should emphasize that these requirements are the floor for plan expectations for compliance staffing and are not the ceiling.

CMS should give states the explicit authority to go beyond the floor established by this rule and require additional standards for compliance staffing for managed care plans, if states deem additional requirements appropriate. For example, states may wish to require that compliance officers who manage the managed care entity's program integrity unit or the Corporate Compliance program have certain certifications or be located in the state. This will help ensure that these units are appropriately staffed to ensure compliance with policy

and contracts and to interpret regulations and statutory provisions that are a critical component of program integrity activities. In addition, states may wish to require that plans have a Special Investigations staff which focuses on or is specifically dedicated to the entity's Medicaid line of business.

101. Plans should be required to refer fraud, waste and abuse to the Medicaid program integrity unit, and states should have the option to also require simultaneous reporting to the State Medicaid Fraud Control Unit (MFCU) (§438.608(a)(7)). We appreciate CMS' recognition that states should have the flexibility to align plan program integrity reporting requirements with the structure and functions of state entities. However, it is most appropriate for the single state agency to be aware of all potential program integrity concerns as early as possible and to ensure the appropriate state response. This will allow the state to oversee and manage the referrals of fraud that are taking place. It would be beneficial for CMS to give states the option to also require simultaneous reporting to the state MFCU, which may be appropriate in the context of some program structures. Allowing states to require all suspected fraud to be reported to the Medicaid agency enhances program integrity by allowing the agency to investigate whether similar issues exist at other MCOs. If the report is only made directly to the MFCU, but not to the Medicaid agency, then the agency loses the opportunity to promptly and efficiently determine whether a system-wide issue exists.

102. States should be permitted to require plans to report potential overpayments and fraud, as well as known overpayments in a timeframe set by the state (§438.608(c)). We agree that it is important for plans to provide information about overpayments in a prompt manner. It is just as important, if not more so, for states to receive information about *potential* overpayments and *potential* fraud in a prompt manner. This allows states to identify and quickly resolve any concerns that threaten the integrity of the program. Therefore, we recommend that CMS explicitly give states the authority to require plans to submit such information in a timeframe, or a window of time, set by the state. States are ideally positioned to determine a timeframe that is realistic and appropriate for plans to report overpayments.

Recoveries

103. States should have the option to allow plans to retain recoveries as proposed in §438.608(d)(1) or use other approaches and mechanisms to incentivize plan engagement in program integrity. States share CMS' goal in putting forward this policy and incentivizing plans to identify fraud and overpayments. While some states prefer the proposed approach, others use a range of different pathways to incentivize these activities that may be more appropriate in the context of that risk-based program. For example, some states set a threshold under which plans may pursue and retain small recoveries during a fixed lookback period. Or states may choose to use other incentives altogether for plan program integrity efforts. As such, states should be permitted to use the proposed approach or elect to use other approaches that align with their program integrity strategy.

Sanctions

104. States appreciate the option to use intermediate sanctions outlined by CMS, as well as other intermediate sanctions (§438.700(a)). It is important for states to have the opportunity to shape sanctions in the context of its Medicaid program. While the sanctions specified at §438.702 are one way to achieve this, there are other approaches that states may find appropriate to use. Therefore, we agree with CMS' recognition that the sanctions specified at §438.702 may be used by states but that states are not limited to these approaches.

Deferral and/or Disallowance of FFP

105. The proposed policy to defer or disallow FFP for targeted services is incongruent with the operation of Medicaid managed care (§438.807). We are unclear how CMS intends to operationalize a policy that would allow for the deferral or disallowance of FFP for targeted services. In particular, it does not seem feasible for CMS to associate a portion of FFP with a specific service under a risk-based, capitated contract. If CMS pursues this proposed policy, the agency should clarify how it intends to implement this approach.

    In addition, we urge the agency to consider and clarify the difference between two very distinct categories of federal-state issues around compliance in managed care. We recognize CMS' pressing fiduciary duty in cases of state non-enforcement of contracts. But we believe these should be handled in a distinct manner from situations where states must operate their managed care program with unapproved contracts. Most often, these situations arise due to process issues and not as a result of deliberate state non-compliance with federal rules. In addition, CMS should clearly articulate that delays in approving rates due to CMS process issues should not result in the disallowance or deferment of FFP (see Recommendation 1).

State Monitoring Standards

106. We are concerned that the requirement for an annual program assessment would add to the vast array of reporting requirements under this rule and would be duplicative (§438.66(e)). CMS proposes this requirement in order to reduce fragmentation in the information it receives from states. However, this fails to streamline the array of reporting processes that states must complete under current regulations, as well as the provisions of the proposed rule. These include the submission of rates, quality strategies, contracts, EQRO reports, data compliance plans, etc. The annual program assessment is also duplicative of many of these other reporting requirements. For instance, the program assessment would require states to report on plan performance on quality measures. This performance would already be captured through the quality rating system.

    In the event that CMS finds it necessary to require these reports, an annual production cycle is unfeasible. Instead, CMS should require a review cycle of every five years, which is often the timeframe used to review other federal-state programs. Likewise, CMS should consider

other opportunities to streamline reporting, such as permitting reports under a Section 1115 waiver to fulfil this reporting requirement and aligning the submission for this report with waiver renewals.

107. States should outline their procedures for plan readiness reviews in their managed care authority, including the components of a plan readiness review, the changes that trigger a review, and the timing for conducting reviews (§438.66(d)). As the preamble of the rule acknowledges, states are already conducting a range of readiness reviews to ensure plans can fulfil their obligations under their contract. These reviews are designed to match the scope of the contract and the responsibilities of the plan. For example, a comprehensive MCO will likely require a different review than a PAHP delivering behavioral health services. States develop their readiness reviews to capture this nuance and should continue to be able to do so. Therefore, we urge CMS to permit states to determine the frequency of reviews, what events would trigger this analysis, and the timing for beginning them. CMS could require states to outline these procedures as part of their managed care authority, including Section 1115 or 1915(b) waivers or in in the state plan.

108. CMS should not require submission of readiness reviews as part of the contract approval process (§438.66(d)(2)(iii)). Requiring the submission of readiness reviews in the contract approval process would add another step to the contract review and approval process, which is already complex and protracted. It is also unclear if CMS staff would have sufficient capacity to review the additional documentation as part of the contract review in a meaningful manner.

    Further, adding this into the contract approval process is not consistent with how states leverage these readiness reviews to date. States conduct readiness reviews after contracts are finalized, or at other points in the ramp up period, to ensure plans have taken the necessary steps to perform all contract functions. For example, states may review plan handbooks or provider directories which plans agreed to develop when the contract was awarded. As such, it does not make sense for states to conduct a review before the plan would have a chance to carry out these activities or has an approved contract.

Third Party Liability

109. We agree that references to specific ICD-9 trauma codes should be removed for purposes of identifying third party liability (TPL) and recognizing state expertise in this area (§433.138(e)). States have decades of experience in identifying the most efficient and cost-effective trauma code edits for the identification of third party liability, as CMS discusses in the preamble. CMS' amendments to these regulations over this same time period reflects this state expertise, as well. In light of this, we support the removal of specific references to ICD-9-CM codes 800 through 999 in favor of a more general description of diagnosis codes that the agency expects states to review.