



November 20, 2017

Ms. Seema Verma
Administrator
The Centers for Medicare and Medicaid Services
200 Independence Avenue, S.W.
Washington, D.C. 20201

Dear Administrator Verma,

On behalf of the nation's Medicaid Directors, we are pleased to offer comments on new directions for the Center for Medicare and Medicaid Innovation (CMMI). As CMS considers what this new direction may entail, we hope that early, robust, and continued engagement with states is embedded in CMMI's work going forward. Medicaid Directors are leading cutting-edge health system innovations at the state level, pioneering approaches that can serve as examples for informing federal work in this critical area. A formal, structured partnership with CMMI can allow Medicaid Directors' operational expertise and strategic vision to inform model development and demonstration design.

The National Association of Medicaid Directors (NAMD) is a bipartisan, nonprofit, professional organization representing leaders of state Medicaid agencies across the country. Our members drive major innovations in health care while overseeing Medicaid, which provides a vital health care safety net for more than 72 million Americans. Medicaid Directors and the teams they lead are at the forefront of delivery system and payment reforms, driving health system transformation via alternative payment models and shifting their programs to be sophisticated purchasers of healthcare value with the aim of improving beneficiary outcomes and ensuring the long-term sustainability of the program.

In these comments, we aim to articulate a vision for renewed state/federal partnership as the backbone for CMMI's future. We also provide specific areas where CMMI can work with states to explore new innovation models for addressing common challenges, such as supporting value-based purchasing initiatives, advancing care coordination for dually eligible Medicare-Medicaid beneficiaries, and tackling high-cost prescription drugs.

State/Federal Partnership: Necessary to Fuel Health System Transformation

NAMD is broadly supportive of the work CMMI has overseen to date. Federal investments in state reform infrastructure via the State Innovation Model (SIM) design and testing grants have allowed states to advance reform goals and execute on previously-developed reform strategies. Medicaid-focused initiatives led out of CMMI, such as the Innovation Accelerator Program and the Financial Alignment Initiative demonstrations for duals, have helped advance long-standing state priorities and supported states with technical assistance resources to design, implement, and sustain key reform activities.

To further enhance this work, Medicaid Directors recommend a more formal and durable CMMI partnership with states. This partnership with states can inform CMMI's thinking and model development early in its processes in order to alleviate misalignment issues. A formal partnership can ensure that states and CMMI are effectively collaborating to minimize duplication; promote strategic, model, and measure alignment; and maximize the likelihood of accomplishing joint goals for enhancing delivery system and payment reform. Below we offer state perspectives on some of the challenges to date that this partnership can help alleviate

Some suggested approaches to structure this partnership are listed here, and NAMD welcomes the opportunity to further discuss these approaches at a future date. We wish to stress that these are suggestions and would require significant additional dialogue to produce the durable and effective partnership that is foundational to continued success.

Proposed Models for State/CMMI Partnership

- Governing Council with state and federal representation, with voting powers to approve CMMI models in the conceptualization and design phases.
- Steering Committee of Medicaid Directors and senior staff tasked with delivery system and payment reform, which CMMI will consult for input on model concepts, operational considerations, and other salient issues.
- Quarterly meetings between CMMI and the NAMD Board (or a subset of NAMD Board members) to provide input on overall CMMI direction.

As part of these models, NAMD further recommends that the federal partnership with CMMI also include perspectives from the Centers for Medicaid and CHIP Services (CMCS) and other relevant federal agencies. Ensuring that the right perspectives are represented in the conversation will facilitate a shared understanding of policy goals and the mechanisms to



achieve them, which in turn promotes the necessary information sharing across states and federal partners to streamline implementation of identified initiatives.

Current Challenges and Misalignments Which Partnership Can Improve

At times CMMI models have not aligned with existing state models and strategies. This has presented challenges for providers who must choose to direct limited resources towards state-driven or federally-driven reform initiatives, when those models may have different reporting requirements, payment incentives, or other distinctions. For example, the Comprehensive Primary Care Plus model (CPC+), when originally released, would have prohibited providers from participating in this model and Accountable Care Organizations (ACOs). This threatened to derail state Medicaid innovations focused on ACOs. Engagement from states early in the model development process would have prevented this significant lack of alignment between models.

Because of a lack of state engagement, some CMMI models have also posed operational challenges for Medicaid agencies, who are expected to be model participants in some capacity but may not be the primary locus point of the model. For example, the Accountable Health Communities (AHC) model required data sharing arrangements between model participants and the state Medicaid agency. While Medicaid data and partnership is a component of success for AHC participants, the specific requirements of AHC in some cases created operational and administrative burdens for states.

CMMI has worked with Medicaid Directors in the past through in-person meetings and calls convened by NAMD to address these issues. This was a positive step forward to build collaboration and alignment between federal and state policymakers who are leading health system transformation. Opportunities to provide written comments on specific models and program areas via the formal comment process are also appreciated, though such processes do not emphasize the unique role of states as program administrators and Medicaid co-financiers. These factors make Medicaid Directors categorially different from other CMMI stakeholders. States are unique drivers of healthcare innovation, and are positioned to effectively plan and implement delivery system and payment reforms that no other stakeholder can replicate. CMMI's mission of promoting innovation would be greatly enhanced by ensuring state perspectives are built into its work from the earliest stages.

Maintaining Federal Commitment to Expanding Value-Based Purchasing Across Payers

As CMS charts a new course for CMMI, Medicaid Directors encourage CMMI to maintain its strategic focus on advancing value-based purchasing across the nation's health care system. States and the federal government have invested significant tax payer resources in developing



the delivery system and payment infrastructures needed to bend the cost curve and reward value over volume. The potential of these investments, which include building all-payer claims databases, designing bundled payment models, supporting provider practice transformation, aligning measure sets, and other strategies, would not be fully realized if Medicare and other federal programs step back from widespread payment reform initiatives.

State Medicaid programs are pioneering a variety of delivery system and payment reform strategies, and their work is producing innovative models that set the benchmark for other payers. However, Medicaid is only one part of the health care payer landscape, and state-led value-based purchasing efforts cannot transform the delivery system without similar vision, commitment, and alignment from Medicare and private payers. CMMI is uniquely positioned to play a role in promoting this alignment. NAMD recommends that CMMI's models continue to prioritize large-scale payment reform, designed to complement existing state efforts in advancing our common goals.

States are still in varying stages of developing value-based purchasing approaches and will need the flexibility to continue to be the incubators of meaningful change. However, Medicare has an opportunity to support states in this critical work by continuing its commitment to wide-scale, comprehensive payment reform. Changing direction in this area could inhibit the reforms needed to truly bend the cost curve and promote improved health outcomes.

Specific Issue Areas to Address with New State/CMMI Partnership

A renewed state/CMMI partnership can be put to work immediately to build on existing successes and to further support and promote Medicaid innovation. States and CMMI share common goals in promoting value in the healthcare system and improving beneficiary health outcomes. CMMI has been active in many of the areas identified below, and we offer state perspectives on modifications to further enhance CMMI's work in those areas. We also offer new program areas where CMMI demonstrations could support meaningful state-led innovation.

Continuing Investments in State-Based Innovation

Payment and delivery system reform requires long-term planning, targeted investments in infrastructure, careful model design, and gradual implementation in order to be impactful and sustainable. The process is lengthy and progress incremental, but at its core is critical for bending the cost curve, improving health outcomes, and improving quality throughout the healthcare system. States have been at the forefront of this work for years, and are continuing to pioneer innovative approaches. CMMI is a valued partner in supporting this work, and NAMD hopes it will continue to play this role going forward.



Specifically, SIM Planning and Testing grants offered by CMMI provided many states with key resource infusions to design and execute on their reform strategies, or to otherwise enhance their existing approaches. As NAMD stated in our [October 2016 response](#) to a Request for Information on future iterations of SIM, we are strongly supportive of SIM and encourage CMMI to utilize a new SIM round or a similar program to continue its support of state innovation. These types of investments must be ongoing, with resources available to states in the planning, design, implementation, evaluation, and scaling up stages of reform. Specific and targeted investment in data infrastructure – measure development, collection, and analysis – is particularly critical, especially for states facing resource constraints which prohibit building or contracting this function.

This support must be paired with a strong emphasis on promoting alignment of programs, models, and quality measurement with existing state strategies. For example, as CMMI considers new models and how they would fit into the Quality Payment Program (QPP)'s Alternative Payment Models (APM) structures, a streamlined pathway for existing state models to be certified as Other Payer Advanced APMs is critical. We appreciate the work that has been done to date on this issue, but continue to call on CMS to ensure that these certification decisions are conducted swiftly and do not pose administrative burdens for states.

Promoting Alignment Across Federal Partners and States

State innovation can be further supported by an articulation from CMS on how CMMI, CMCS, Medicare, and the Medicare-Medicaid Coordination Office will engage with states in model design and implementation, and how information will be shared and policy direction solidified across all partners. In the past, states have encountered barriers in participating in CMMI models due to difficulties in attaining necessary regulatory authorities from CMCS. Going forward, CMMI models should be accompanied by streamlined approval pathways for these authorities, whether they be waivers, State Plan Amendments, modifications to managed care contracts and rates, commitment from Medicare regulators to support state participation in CMMI models, or other changes. More broadly, CMMI can work with Medicare and the states to ensure Medicare models are aligned as closely as possible with state-driven initiatives and frameworks.

Refining CMMI Initiatives for Dually Eligible Medicare-Medicaid Beneficiaries

The dually eligible Medicare-Medicaid population is one of the most complex, frail, and challenging populations to manage. In 2012, duals represented only 15% of the national Medicaid population, but accounted for 33% of program spending, according to a [fact sheet](#) from the Medicare-Medicaid Coordination Office (MMCO). These statistics reflect a population



with low income and complex care needs, which include both acute care and long-term services and supports. Coordinating coverage policies, benefit design, financing, and care delivery between the Medicare program and the Medicaid program has further exacerbated the challenges associated with the duals population.

The work of CMMI, in partnership with MMCO and states, has been invaluable in addressing the needs of duals in the past several years. CMMI's Financial Alignment Initiative (FAI) demonstrations, as well as MMCO's work on Duals Special Needs Plans (D-SNPs) in Medicare Advantage and Programs of All-Inclusive Care for the Elderly (PACE), represent significant progress on duals issues. Early results of FAI demonstrations in Washington show savings and improved outcomes for covered duals, and this progress should be maintained going forward.

Modifications to the FAI demonstrations could further enhance their adoption and sustainability across the states. In particular, Medicare rules allowing beneficiaries to opt out of an FAI managed care demonstration at any time poses significant challenges for states. This opt-out provision, intended to safeguard beneficiary choice, is disruptive to state efforts in building and sustaining care coordination capacity. NAMD recommends that CMMI consider modification of the managed care FAI demonstrations to allow enrollment lock-in periods of at least one year, with beneficiary opt-outs only for cause. This change would promote continuity of care, allow predictability in coverage and financing across demonstration participants, and promote the overall objectives of the demonstration.

CMMI should also work to facilitate streamlined data sharing between Medicare and states. The State Data Resource Center (SDRC) has produced significant inroads in state access to Medicare data, as well as technical assistance resources to effectively leverage Medicare data. NAMD supports these efforts. However, states continue to identify issues with timely access to Medicare data as an impediment to more effective management of the duals population. CMMI, Medicare, and Medicaid partnership on this foundational aspect of effective program management should be a continued priority, and resources designed to support data sharing should be independent of any one model or demonstration.

Lastly, CMMI should work with states who are in varying stages of capacity to take on care integration for duals. Current work, such as the FAI demonstrations and the proposed duals Accountable Care Organization model (since withdrawn), appear oriented towards more advanced states who are prepared to take on significant responsibilities. These advanced opportunities may be appropriate for some states, but not all states are prepared to take on this scope of work. CMMI should consider developing a continuum of duals-focused demonstration opportunities to meet states where they are, with the goal of building up additional state infrastructure to further enhance work in this area.



Promoting Progress on Behavioral Health Integration

Weaving behavioral health services more seamlessly into the fabric of the acute care delivery system is a long-standing priority of Medicaid Directors. This work requires collaboration at the state interagency level, aligning purchasing strategies, and promoting physical and behavioral health integration at the provider level.

Data sharing across providers in a care team is a core component of robust behavioral health integration efforts. Unfortunately, federal privacy rules on substance use disorder data under 42 CFR Part 2 pose a barrier to this data sharing and collaboration. The separate privacy rules under 42 CFR Part 2, which do not align with those governing other health data under the Health Insurance Portability and Accountability Act (HIPAA), prevents individuals with a substance use disorder from benefiting from advances in care coordination and delivery system reform. The rules also keep these individuals from receiving the benefits of advances in health information technology. As such, 42 CFR Part 2 has limited states' ability to comprehensively transform care for these individuals. NAMD recommends CMMI develop and test models to facilitate enhanced data sharing between providers as part of broader state behavioral health integration strategies.

As states continue to explore strategies to promote integration and build capacity to provide behavioral health services across the care continuum, one key issue continues to pose a significant barrier: the Medicaid Institutions for Mental Disease (IMD) exclusion. The IMD exclusion was set in Medicaid statute at the time of the program's creation in 1965, and prohibits federal payment for inpatient psychiatric services at facilities with more than 16 beds. This prohibition has produced significant challenges for states to ensure appropriate access to critical mental health and substance use disorder services for vulnerable individuals in recent years. The ongoing opioid epidemic, and state efforts to enhance substance use disorder treatment capacity to address it, underscore the barriers created by the IMD exclusion. Further, the IMD exclusion's restrictions on inpatient psychiatric services is in tension with long-standing federal and state work to promote parity between physical and behavioral health services.

CMS has been responsive to state requests to modify or waive the IMD exclusion for treating substance use disorders, specifically via a SUD-specific 1115 waiver model. Similar flexibility in providing inpatient mental health services is currently lacking. While CMMI did explore targeted flexibilities via the Medicaid Emergency Psychiatric Demonstration (MEPD), this demonstration only lasted two years, which presented challenges in evaluating its impact. NAMD strongly encourages CMMI to consider continuing the MEPD or to otherwise explore

avenues to test models that waive the IMD exclusion, such as part of a broader behavioral health treatment capacity-building initiative.

Addressing High-Cost Prescription Drugs

The introduction of highly specialized, high-cost prescription drugs to the market in recent years has posed significant challenges for healthcare payers, including Medicaid programs. The trend of breakthrough therapies targeting highly specific patient populations, and in some cases offering curative therapies for specific conditions, represents significant opportunities for improving the nation's overall health – but only if costs are appropriately managed. Medicaid, unlike other payers, is required by federal statute to cover every drug approved by the Food and Drug Administration (FDA), in exchange for mandatory rebates under the Medicaid Drug Rebate Program (MDRP). States are also able to negotiate additional supplemental rebates on top of the MDRP's mandatory rebates. Prior authorization criteria can be put in place to incentivize the use of one drug over another, but these criteria may not result in complete exclusion of a product from coverage under the MDRP.

While the MDRP has proven effective in the past for ensuring Medicaid programs are able to provide comprehensive prescription drug benefits in a fiscally responsible manner, recent trends in drug pricing and breakthrough approval pathways indicate room for further experimentation. Breakthrough therapies may not have competitors in their drug class, which inhibits states' ability to negotiate supplemental rebates. States, unlike commercial payers or other public payers, may not exclude coverage of these breakthrough products, even if the clinical evidence base for their efficacy does not match the characteristics of a given Medicaid population.

CMMI can work with states to test new models of coverage and payment for prescription drugs in order to address these challenges. Approaches could include:

- Demonstrations testing closed formulary approaches in Medicaid, whereby Medicaid programs may cover a specified number of products in a given therapeutic class and exclude coverage of other products. Prior authorization procedures could ensure beneficiary access to non-formulary products when medically necessary. This model could mirror prescription drug benefits in Qualified Health Plans (QHPs) on the Exchanges.
- Invest in Medicaid pharmacy value-based purchasing capacity. This could include prioritizing enhancing condition-specific surveillance and data collection capacities, which could in turn support specific alternative payment models for the Medicaid pharmacy benefit. These models could:

- Condition payment for a therapy based on an individual’s response to the therapy within a specified time period (particularly for managing a chronic condition);
- Condition payment based on a successful course of treatment (more appropriate for curative therapies);
- Base payment on projected utilization of a therapy in an identified Medicaid population over a specified time period, with payment reconciliation for over or under-utilization;
- Make provisional coverage of a product available for products approved on an accelerated approval pathway, on the condition of additional post-approval evidence development; or
- Other models identified by states and CMMI.

Testing the Full Range of APMs with Federally Qualified Health Centers

FQHCs are vital partners in delivering primary care services and other critical services to Medicaid beneficiaries. However, as states continue to move away from volume-based reimbursement models to alternative payment models that fully align both quality, outcomes and payments for a broad group of providers, FQHCs continue to be excluded from many such strategies. FQHCs, which are paid on a volume-based per-visit basis under the Prospective Payment System (PPS), are unique in their ability to not be routinely included in full value-based APM strategies, which would include risk-based models.

Under current law and regulation, the PPS represents a floor for FQHC rates. States have the option to structure APMs which pay at least the PPS and can reward high-quality care with a rate above the PPS, and some states avail themselves of this flexibility. However, states do not currently have the ability to fully financially align quality and outcomes, even when evidence has shown that risk-based payment methodologies are incentivizing quality improvement and improved outcomes in other sectors of the provider landscape. As FQHCs expand in certain states, the ability to ensure quality outcomes and incentivize performance becomes more pressing as part of a wider delivery system and payment reform strategy.

CMMI can play a constructive role in working with states to test the full array of APMs with FQHCs, including value-based and risk-based reimbursement models that align quality, outcomes and costs. These demonstrations could be small-scale and targeted towards willing FQHCs that demonstrate the capacity to onboard risk, in partnership with the state and its managed care entities, if applicable. We encourage CMMI to explore these approaches and to develop models which incentivize high-quality FQHC performance while ensuring their core missions remain achievable.



Enhancing the Innovation Accelerator Program

NAMD supports the topical technical assistance opportunities CMMI has provided to states under the Innovation Accelerator Program (IAP). The IAP's focus areas since its initiation – including substance use disorder; high-cost, high-need beneficiaries; behavioral health integration; alternative payment models; and others – generally reflect state Medicaid agency priorities. With the concrete partnership described above, we anticipate CMMI will continue targeting IAP tracks towards salient topics going forward.

IAP's technical assistance can be further refined with additional engagement and partnership with states. In particular, CMMI should prioritize ensuring its IAP contractors are fully immersed in participating states' Medicaid program features and populations. Medicaid Directors have expressed that, depending on the IAP track, some contractors have required significant time being brought up to speed on a state's program before effective technical assistance could be provided. The time and resources spent educating IAP contractors created low-value work for states, which is not the goal of IAP.

Additionally, in the past CMS has required state participation in certain IAP tracks in order to secure separate regulatory flexibility – for example, early 1115 SUD waivers were conditioned on the state completing the IAP SUD track. This policy presents procedural challenges and demands on state resources and staff time. We encourage CMMI to consider pathways for IAP technical assistance that prioritizes high-value and high-impact work, particularly when IAP participation may be expected to achieve a separate waiver or other regulatory authority.

Thank you for the opportunity to provide these comments. NAMD and our members stand ready to engage with you to achieve the vision we have articulated here, and look forward to a follow-up conversation.

Sincerely,

A handwritten signature in blue ink that reads "Judy Mohr Peterson".

Judy Mohr Peterson
Med-QUEST Division Administrator
State of Hawaii
President, NAMD

A handwritten signature in black ink that reads "Kate McEvoy".

Kate McEvoy
State Medicaid Director
State of Connecticut
Vice President, NAMD