

June 3, 2019

Seema Verma Administrator The Centers for Medicare and Medicaid Services 7500 Security Boulevard Baltimore, MD 21244

Dear Administrator Verma,

On behalf of the nation's Medicaid Directors, NAMD is pleased to offer comments on CMS's proposed rule concerning interoperability and patient access to health data [CMS – 9115 – P]. While we support the ongoing work to improve Medicaid systems, data quality, and the use of data to promote more coordinated and effective care, we are concerned that the timelines and operational aspects of implementing this proposal will pose significant challenges for states. We recommend, at minimum, two years of implementation time after final publication of the rule, and strongly prefer five years of implementation to ensure success.

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 are familiar with the opportunities of leveraging data systems to drive coordination and improvement activities in today's complex health care landscape. That complexity, however, also creates significant challenges for states to navigate. State experiences with systems redesign and modernization in a number of program areas, including eligibility and enrollment, implementing modular Medicaid management information systems (MMIS), and the transformed Medicaid statistical information system (T-MSIS), reveal the importance of properly formulating the strategy behind a systems change and allocating sufficient time and resources to achieve success. Medicaid systems work is often lengthy, expensive, and resourceintensive.



It is precisely for these reasons that NAMD must raise concerns with key aspects of what this proposal seeks to accomplish. First and foremost, the effective date of July 1, 2020 for the vast majority of the rule's changes is not a feasible target for states, managed care entities, electronic health record (EHR) vendors, and providers to come into compliance. The scope of operational changes to make, modifications to systems and business processes, development of new procedures, and making associated state-level regulatory (and potentially statutory) changes will require additional time than this rule contemplates. Current state system redesigns may need to be revised to account for this work, which would require contract modifications, procurements, and other lengthy and resource-intensive processes that cannot realistically meet such a compressed compliance date. Additionally, for states that have already begun implementing personal health records for their Medicaid beneficiaries, this rule's envisioned approach would create multiple new applications that may cause confusion or concern among individuals who are accessing their data today.

In the Medicaid program, the rule envisions states and their contracted managed care entities to implement open Application Programming Interfaces (APIs) which are able to share a variety of data with third-party applications within one business day. Additionally, states must develop a testing and monitoring mechanism to ensure the API is sharing data appropriately and complying with applicable privacy laws and regulations, including the Health Insurance Portability and Accountability Act (HIPAA) and 42 CFR Part 2's substance use disorder (SUD) privacy protections. States are also required to develop a process for identifying third-party applications that pose risks to the state's health information systems. Lastly, states and managed care entities are expected to develop beneficiary education materials to assist individuals in protecting their health information, making informed choices about third-party applications to use, and how to submit complaints to relevant federal entities. The scope of these activities should not be underestimated.

If CMS does move forward with this rule, NAMD encourages more thought to be given to its overall objective of providing Medicaid beneficiaries with detailed health data and information. Medicaid claims data and managed care encounter data can be complex and is not currently designed in a manner that will easily support beneficiary empowerment. While we recognize that this information can be creatively utilized by third party app developers, we note that there may be a beneficiary expectation that the state, the managed care plan, or another entity providing health information should have a role in educating individuals on the best uses of that information. We support the goal of empowering Medicaid beneficiaries to make informed decisions about their care, but also recognize that achieving that goal will take time and creativity from all entities involved. We encourage CMS to work with states, managed care



plans, and providers to explore promising practices for beneficiary education around safe and secure use of health data.

On a more technical level, states have some operational and business process issues to navigate in achieving the aim of more accessible beneficiary data. States will need to assess whether their current MMIS is able to interface with APIs. If not, this systems change will need to be put in place, which may entail lengthy procurement processes. States will also need to design and implement the data checks and infrastructure to ensure the API is appropriately accessing data and complying with necessary privacy protections. Additionally, states must develop a mechanism to gauge the relative security of apps with access to the state's health systems, as well as put processes in place to inform beneficiaries of the relative risks of requesting information with certain apps, as suggested in the HHS Office of Civil Rights (OCR)'s Frequently Asked Questions on this topic. Successfully implementing all of these necessary activities will require substantial state resources, increased capitation rates to managed care plans to support their compliance, and will likely require contractor support for state systems and business process modifications. To the fullest extent possible, we encourage CMS to provide enhanced FMAP opportunities for states to conduct these activities, via the Implementation Advanced Planning Document (IAPD) process or other process, as appropriate.

We appreciate OCR's FAQs clarifying state and plan responsibilities and potential liabilities as covered entities in sharing protected health information (PHI) with third party applications. We specifically appreciate the clarification that states do not bear liability for data breaches of an app receiving PHI (unless the state owns the app or has a business relationship with the app developer) or if unencrypted PHI shared at the request of a beneficiary is inappropriately accessed during transmission. However, while these FAQs provide a more certain legal picture for states, they raise an overarching question of how beneficiaries will use their health information – as articulated above – and how states may be held responsible in the public's perception if PHI is accessed or used inappropriately. Developing a strategy to navigate these complex issues will require careful deliberation. States would greatly benefit from additional CMS guidance on these issues, particularly around effective strategies for assessing the levels of risk of various third-party applications.

One potential pathway to provide certainty for states is for CMS to allow state T-MSIS files to serve as the beneficiary data source for third-party applications. T-MSIS would have advantages in encompassing both claims and encounter data and in residing within CMS, which could facilitate a more streamlined approach to secure data sharing with third parties. However, T-MSIS does have limitations. First and foremost, if T-MSIS is used in this manner, CMS must work proactively with states to ensure the accuracy and validity of the data prior to



it being shared with beneficiaries. That said, with appropriate safeguards T-MSIS could be a viable approach to reduce burden on states in achieving the aims of this rule.

We do wish to highlight one aspect of the rule around CMS's expectations for increasing the frequency of eligibility information for dually eligible Medicare-Medicaid beneficiaries ("duals"). CMS proposes daily exchanges of Medicare Part A and Part B buy-in data and daily exchanges of state MMA data files, effective April 1, 2022. Currently these files must be shared with CMS on at least a monthly basis, with 31 states currently submitting daily buy-in data and 13 states currently submitting daily MMA files. While the effective date for these proposals is more realistic than the July 1, 2020 effective date for the remainder of the rule, we do note that states not making daily exchanges currently will need to revise systems and business processes to support an increased frequency of exchange, with associated costs. We anticipate the proposed effective date will be sufficient for these changes, and encourage CMS to assist states and modify its own processes and systems to effectively leverage daily data exchanges to support enhanced care for duals. However, for overall unity in the rule's proposed changes, we encourage CMS to consider aligning these changes with an overall extended implementation timeframe of at least two years – and ideally five years – for the remainder of the rule's provisions.

NAMD thanks CMS for its consideration of state views on these important interoperability and data sharing issues. Given the complexity and nuance of these issues, the significant modifications likely needed for current state systems, and the need for beneficiary education to maximize the impact of their health data, we view a delay in the effective date of two to five years for these proposals as necessary to achieve success. NAMD and our members stand ready to further engage with CMS and other stakeholders to empower beneficiaries in making informed and effective decisions about their care.

Sincerely,

Kate McEvoy State Medicaid Director State of Connecticut President, NAMD

Beth Kidder Deputy Secretary for Medicaid State of Florida President-Elect, NAMD