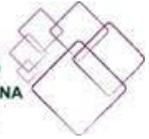




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JUSTICE CENTER

DISABILITY RIGHTS
NORTH CAROLINA

Champions for Equality and Justice



July 20, 2016

Vikki Wachino
Director for the Center for Medicaid and CHIP Services (CMCS)
Centers for Medicare and Medicaid Services

Via Electronic Transmission

RE: Comments on NC Medicaid Reform Section 1115 Demonstration

Dear Ms. Wachino:

Thank you for the opportunity to submit these comments on North Carolina's Medicaid Reform 1115 Demonstration Application.

North Carolina has proposed a profound shift in the way that it delivers Medicaid services. It will require significant restructuring and reorganization to build this complex system. The application lacks significant detail about the redesigned system. While the aspirations of the program are commendable, the shift to capitated managed care and the fundamental changes it requires present serious risks to beneficiaries, providers, and other stakeholders. North Carolina Medicaid has a history of rocky system transformations, such as more than one mental health reform effort and the implementation of NCTracks (its provider payment system) and NC FAST (its eligibility system). It is far from clear that the state has the technical and regulatory infrastructure sufficient to ensure that the proposed system can operate properly. CMS must take great care to ensure that the beneficiaries, providers, and other stakeholders have a smooth transition and continued access to services. For this reason we ask that CMS withhold approval of this waiver until the state agency provides more information concerning its plan.

Specifically, we raise the following questions and concerns for CMS to require assurances about before it approves this application.

I. Demonstration Initiative #1: Building a System of Accountability for Outcomes.

North Carolina has proposed a system of Prepaid Health Plans (PHPs), in which Provider Led Entities (PLEs) and Commercial Plans (CPs) will operate side by side. The application fails to properly explain how this system will actually work.

Provider Led Entities (PLEs). PLEs will be completely new to North Carolina Medicaid and are relatively new to Medicaid nationwide. The application lists a variety of possible spending options, including shared savings. (Demonstration Application at 18). The question of which spending option plans employ is fundamental to the system, therefore it concerns us that this has not been specified in the waiver application. When will it be determined which options are used? Who will participate in this decision and on what criteria will it be based? If shared savings are used, how will they be calculated? This information should be provided before the application is approved.

Use of shared savings for PLEs raises serious due process concerns because, depending on the structure of the PLE, the providers themselves may have direct motivation to informally deny or discourage use of services. In an MCO system, a treating provider initially determines whether a service is medically necessary, then the MCO utilization management reviews a request for the service to determine whether it will be covered. The waiver fails to address how this will work in a PLE where the treating provider and utilization review are part of the same entity. CMS should require PLEs to have robust protections against conflicts of interests, including strong firewalls between those who are determining medical necessity and those who have responsibility for ensuring that shared savings goals are met. The state agency should be required to address how formal and informal denials of care will be measured, which is critical to enable CMS to fully evaluate the demonstration.

The application raises other questions about provider participation and network adequacy in PHPs. It does not indicate, for example, whether PHPs will be required to contract with North Carolina Community Care Networks (N3CN) care managers. If not, the state agency should be required make clear how these important responsibilities will be transitioned – what will be the state’s responsibilities and what will be the PHPs’ responsibilities?

Nor does the application state whether PHPs will be required to contract with Community Pharmacy Enhanced Services. The state agency needs to explain how these services will be covered and paid for. The application also does not discuss how NC DHHS will ensure that PHPs comply with Medicaid requirements guaranteeing access to family planning and women’s health services, as required by federal Medicaid law. 42 U.S.C. § 1396d(a)(4)(C); 42 C.F.R. § 438.206(b)(2). MCO Beneficiaries must also be given access to a second opinion, in or out of the network. 42 C.F.R. § 438.206(b)(3). This right must be afforded to PLE enrollees and should be guaranteed before the application is approved.

Furthermore, there is little explanation in the application of how will NC DHHS assure network adequacy in rural areas, given that provider participation is low in those areas. We understand Initiative #2 proposed ideas on how to build up access in rural areas, but as this is part of the demonstration it will be years before the effect of those efforts will be seen. In the meantime, NC DHHS must assure that it will provide adequate network adequacy in rural areas until Initiative #2 is successful. Moreover, the application does not mention non-emergency Medicaid transportation. In the past, DSS offices have largely been responsible for providing Medicaid transportation. The state must explain who will be responsible under the waiver.

Finally, the application mentions but does not make clear how NC DHHS will continue to use NCTracks as part of this reformed system. NC DHHS will need to do significant work on this aspect of the reform, given the complexity of the system and the significant changes that would be needed in how prior approval and payment occur. If NC DHHS decides not to use NCTracks, the state agency must address what system for tracking expenditures will replace it, what the system requirements will be for the PHPs, and how the transition from one system to the other will occur.

Progress Towards Integrated Behavioral and Physical Health. NC DHHS says in its application that it plans to integrate primary care and behavioral health by requiring the Local Management Entities already operating as MCOs for behavioral health services under a 1915b/c waiver to begin taking some responsibility for physical health and by requiring physical primary care providers operating under the new MCOs to be responsible for some persons with behavioral health issues. Very little detail on this proposal is provided. We have serious concerns that this will not work, much less be operational by 2018. The concept raises many questions which are unanswered by this document. Exactly what services for which enrollees will be the responsibility of each MCO? For example an enrollee may need hospitalization or in-home care for a combination of physical and behavioral health issues. Will there be contracts between the LME/MCOs and the PHPs? How will integrated behavioral and physical health plans be reimbursed if the PHPs and LME/MCOs are receiving a separate payment? If a primary care provider in a PLE requests behavioral health services, can the LME/MCO utilization management deny the request? Who will have the final say between the two? How will NC DHHS ensure that enrollees are not passed between the two plans, unable to obtain a service from either? What if a provider is in one network and not the other? What mechanisms will there be to ensure that these individuals have an overall care plan such that their complex needs, records, and treatment plans are communicated to all necessary treating clinicians and referrals are followed up on to ensure care? These questions should be considered and addressed before CMS approves this demonstration.

NC DHHS proposes to provide access to individuals with severe mental illness and substance use disorders. (App., p. 15). Several questions are unanswered about this issue. What are the details of how this will happen? If there is a plan, will the details be made public? The application describes how LME/MCOs are “reinvesting managed care savings to support the integration of physical healthcare.” (App., p. 15). Will NC DHHS require that this practice be continued and expanded? How will quality control and monitoring be done to ensure that services are truly integrated?

Enrollment. The application does not explain how auto-enrollment will work (although an enrollment broker is mentioned). The state agency’s Legislative Report discusses plan assignment, but does not explain how beneficiaries will be matched with a PHP when NC DHHS will not have claims data for new Medicaid beneficiaries. It is important that an opt-out mechanism be provided for those auto-enrolled, as well as strong consumer education to beneficiaries about disenrollment rights. Moreover, NC DHHS must include protections against illegal marketing by plans into a particular plan. This will be particularly important if PLEs are not subject to federal managed care regulations.

II. Demonstration Initiative #2: Better Health in Our Community

Person-Centered Health Communities (PCHCs). DHHS plans to transform existing Primary Care Medical Homes (PCMHs) into PCHCs. We support the goal of coordinated, person-centered care. However, we are concerned that the transition may not preserve the benefits and value of the existing PCMCs. In addition, we fear that the value that Community Care North Carolina (CCNC) has provided for so many years will be lost. Which CCNC functions and characteristics will be preserved? How will this happen? What role will CCNC be permitted to play in the new system?

We support NC DHHS' goal of integrating population health management as a part of the reformed system. However, more details are necessary before approval of this plan. The application indicates that comprehensive health assessments will include "social determinants of health data." What sort of data? Which social determinants of health? To what extent will this be at the discretion of the PCHC, or will there be a uniform prescription from the PHP or NC DHHS?

We are concerned that the section of the application discussing person-centered care does not indicate that NC DHHS will require the PHPs to conform to the standards set forth for the Medicaid program generally. In both the HCBS regulations and the MLTSS guidance that predated those regulations, it is clear that CMS intended a person-centered plan to be led by the individual and reflects their informed choice from an array of options. *See, e.g.*, 42 C.F.R. § 441.301(c). It is also crucial that a person-centered plan have clear conflict of interest standards. This is particularly important in the demonstration NC DHHS is proposing where the PCHC is performing so many of the roles and shared savings incentives are explicitly designed to provide efficient care - in other words, to save money.

NC DHHS must ensure that any care planning that is done by these entities adhere closely to the standards of person-centered care, and possibly have additional protections, to ensure that care planning involves: (1) fully informing a person of all of their care options, not only to what the PCHC recommends; (2) protections and provision of necessary assistance to allow a person to truly lead the care planning based on their choices; and (3) protection against conflicts of interest. North Carolina beneficiaries have had troubling experience with care planning in recent years, especially with LME/MCOs, where person-centered planning is influenced by budgets and care coordinators to the detriment of enrollees' desires and in a way that circumvent due process. Many individuals who experienced the switch from FFS to managed care reported that they get the impression that their care is far less important than the entity saving money and that the LME/MCO care coordinator is not interested in helping them actively access the care and services they need. Litigation resulted from this issue and the state could again risk such litigation if this issue is not addressed before the waiver is approved.

We also have concerns about the NC DDHS plan to incentivize the use of non-face-to-face encounters, including telemedicine programs. While technology may enhance timely access to care for parts of the population, it can create barriers for those that do not have ready access to the necessary technology or who need face to face interaction for culturally competent care or

due to their disabilities. Rather than focusing largely on telemedicine, the state should broaden access by allowing providers to bill for treatment mechanisms other than a face-to-face visit. Otherwise, we fear that over-reliance on telemedicine may harm the quality of care and discourage individuals from accessing necessary care.

Enhancing Outcomes for Children and Families in the Child Welfare System. We commend NC DHHS for including these provisions in its proposal. We wholeheartedly support the extension of coverage to parents of children in foster care. We also support NC DHHS' plan to develop a single PHP for children in foster care that is tailored to their needs. Eliminating the need to change plans when a child is placed in a foster home would also help. However, many details about this proposal are missing, making it difficult for CMS to determine what is being demonstrated and how that will be measured. For example, what will happen when children go back to their home? Plans must be made to accommodate children who are placed in foster homes for short or indefinite periods.

Supports for Children and Youth with Special Health Care Needs. The definition of Children and Youth with Special Health Care Needs (CYSHCN) is under-inclusive. In order to properly support these children, the definition should be sufficiently broad to allow more children who need additional services to access those services early. A child with a chronic health condition should not have to deteriorate to the point of medical fragility in order to be treated as a CYSHCN. In addition, children with mental health diagnoses should be included. While many of these children will receive their mental health services through the LME/MCOs, many children with mental health diagnoses will receive treatment from their primary physician. In addition, children with mental health diagnoses who receive services from an LME/MCO should be included in this CYSHCN group, as such children often need a great deal of care coordination and have complex pharmacological profiles. Children receiving services from an LME/MCO will be receiving services in a fractured system and therefore need more, not less medical home support. In addition, it is not clear what supports will be part of this part of the initiative or how children will be identified. All children screened through EPSDT and identified as requiring developmental services, mental health services, physical therapy, or other services that indicate special health care needs should be considered a CYSHCN until it is determined such services do not help in correcting or ameliorating the child's conditions.

Moreover, children with special needs currently have difficulty accessing services that are required under Medicaid's Early and Periodic, Screening, Diagnostic, and Treatment (EPSDT) requirements. For example, many children with behavioral health issues face severe difficulties in obtaining appropriate behavioral health services due to MCO network inadequacy and inadequate provider rates, particularly for more specialized types of care. How will NC DHHS ensure that the significant barriers to obtaining EPSDT covered services are not carried over into the new capitated system? The application states that PHPs will be "held accountable" for providing this care, but does not explain how. NC DHHS should be required to include detailed benchmarks and specifications in its contracts with PHPs that assure network adequacy, to closely measure whether prescribed services are delivered, and to monitor grievances and appeals related to EPSDT services.

III. Demonstration Initiative: Supporting Providers through Engagement and Innovation.

Essential Providers. NC DHHS should be required to designate additional types of providers as essential. For example, the list does not include HIV providers reimbursed under the federal Ryan White CARE Act.

IV. Evaluation

It is difficult to see how this demonstration can be adequately evaluated without more details about how outcomes will be measured and monitored. How will the evaluation measure quality, health outcomes, consumer satisfaction, and access to providers? Will these measurements permit “apples to apples” comparison between the two models (PLEs and traditional MCOs)? CMS should require this information before approving the application.

V. Other Issues

Grievances and Appeals

The authorizing state legislation for this application confers responsibility for grievances and appeals upon the PHPs. Given this fact, it is surprising and disappointing that the application does not mention this. Opportunity for notice and hearing and to file a grievance with a managed care plan is, of course, required by federal (and state) law. These rights are particularly important in a capitated environment, given the inherent incentive to deny, delay, or reduce services. As discussed above, this risk may be heightened when shared savings are at stake. It is not clear whether the process for seeking a fair hearing will remain the same as it is now for the LME/MCOs – the state agency should be required to specify this. Will the process be the same for PLEs as for CPs? How will informal denials without notice of appeal rights be prevented, particularly for PLEs, where the treating clinician is part of the PLE? CMS should also require that NC DHHS implement uniform grievance processes for all PHPs.

Consumer Protection

While the authorizing state legislation provides that Chapter 58 of the North Carolina General Statutes will govern PHPs, NC DHHS and the NC Department of Insurance (DOI) have recommended that PHPs be exempt from the remaining requirements of that chapter. Instead, “DHHS. . . will incorporate key protections” into PHP regulations or contracts. (Legislative Report: Transformation and Reorganization of North Carolina’s Medicaid and NC Health Choice Programs, p. 8). We urge CMS to require DHHS to include all consumer protections in state regulations as well as the PHP contracts. In particular, the following protections are imperative:

- a. Right to use out-of-network providers if the existing provider network is inadequate (NCG.S. § 58-3-200(d))
- b. Standing referrals to specialists (NCG.S. § 58-3-223)
- c. Appeal rights (NCG.S. §§ 58-50-61(a)(6), (h)(k)(l), 58-50-77, 58-50-62, 58-50-79)

- d. Definition of medical necessity (NCG.S. § 58-50-61(12), 58-3-200(b))
- e. PHP reporting requirements (NCG.S. § 58-3-191)
- f. Provider protections against retaliation for appealing. (NCG.S. § 58-50-62(j)).
- g. Providing information to Medicaid beneficiaries about utilization review procedures (NCG.S. § 5858-50-61(e)(3), (m)).

There are other consumer protections that should be provided to Medicaid recipients as well, which are described in the NC Institute of Medicine's recent Guide. *See Pam Silberman and Asheley Cockrell Skinner, A Consumer's Guide to Health Insurance and Health Programs in North Carolina*, Ch. 24, "Consumer Protections and Glossary," at 184, available at <http://www.nciom.org/wp-content/uploads/2003/01/hlthinspgms.pdf>

Beneficiary and Public Engagement

We are very concerned that there is almost no reference in the application to beneficiary involvement in the development and operation of important aspects of the reformed system.

One of the primary aims of this proposed demonstration is to improve provider engagement in managing care and to support those providers. In comparison, the application mentions very little about how beneficiaries and their families will be offered support or input through these innovations. We support NC DHHS's goal of engaging and supporting providers, as we recognize that a Medicaid system cannot provide quality services without a good supply of qualified providers. We are concerned, however, that while DHHS recognizes that providers are going to need significant support to make this system work, the application barely recognizes the fact that beneficiaries' voices matter as well, as they are the ones that hurt if the state's Medicaid system fails.

A robust beneficiary protection system that meaningfully addresses complaints, provides education and technical assistance to beneficiaries and their families, and provides assistance with navigating denials of services is critical to the success of this demonstration, especially in the early years of creating and transforming this system. We are therefore pleased that the application indicates that the reformed system will include a beneficiary support system. However, NC DHHS appears to propose that the system would serve only those who receive LTSS. (App. at 55). This would not comply with new federal managed care regulations, which require a beneficiary support system for all enrollees. *See* 42 C.F.R. § 438.7. Moreover, this language does not provide sufficient protection, especially considering the extent of the choices in the proposed system, the changes in the system regarding how health care is delivered and who is making decisions, and North Carolina's history with beneficiary protections and satisfaction under managed care.

As evidenced by its new regulations, CMS has recognized that there is a need for an ombudsman or beneficiary support system in managed care, particularly if those individuals have high, chronic needs. As discussed previously, this reformed system would increase the risk and incentives closer to the beneficiary and may affect a provider's ability and willingness to be an advocate for a beneficiary's needs. Thus, a robust beneficiary support system is necessary for all enrollees, not only those who receive LTSS. Such a system would not only provide needed protections for beneficiaries, but would enable the state to gather critical information about

whether systems are working and where issues may be that are affecting the success of this demonstration. Importantly, such a system would also provide much-needed balance to this provider focused demonstration. For a reform project focused on health outcomes and social determinants of health, the proposal is missing one of the most important determinants—the individual’s buy-in to their plan of care created and overall participation. A system that lacks a strong, conflict-free ombudsman program that can effectively respond to complaints and help beneficiaries navigate denials of services will not serve beneficiaries well and will ultimately fail to meet the aim of providing better experience of care and better health in the community.

This is particularly true because the state does not have a strong history of providing a meaningful complaint process for beneficiaries experiencing problems with managed care under the LME/MCOs. Beneficiaries and their family members have struggled to navigate that system and in the past the state often offered no visible, meaningful mechanism for complaint other than to the LME/MCOs themselves, which often failed to resolve issues in a fair manner. Therefore, we urge CMS to require NC DHHS to include a beneficiary support system that is free of conflict and will support all beneficiaries by providing at least training, choice counseling, help with understanding managed care including enrollee rights and mechanisms for advocacy, and assistance in navigating the grievance and appeal process.

The Medicaid program works best when it includes active input and participation from the citizens it serves. The application does not promise beneficiary input (or other public input, for that matter) into further development of the system beyond this initial comment period. This is especially concerning because the application leaves the vast majority of details about the new system to be developed in the future. Nor does the application specify how beneficiaries and their families will be involved in making changes to the system once it is operating. CMS should require the state agency to do so.

For example, NC DHHS should be required to solicit beneficiary and other public input as it develops the contract RFPs. This is arguably the most important document in this proposed system, as the LME contracts define the system and the services enrollees will receive. PLEs will have outcome and process based quality measures and benchmarks. The application does not indicate, however, how these will be formulated and who will be involved. Moreover, the application states that the state agency will consider “recommendations from Medicaid advisory groups” when finalizing network adequacy standards(p. 48). Which advisory groups? What will be the forum? Will this provide an opportunity for formal or informal comments by consumers and their advocates? CMS should require answers to these questions before approval.

To ensure beneficiary input and participation into the reformed system once it is operating, we have repeatedly urged the state agency to require that each Prepaid Health Plan (PHP) includes beneficiaries in the governance structure of each PHP, as a number of other states have done.¹ We also recommended the state agency establish a Medicaid Citizens Advisory Council

¹States that require involvement of enrollee populations in governing accountable care organizations (both MCO and PLE types) include Maine, New Jersey, and Oregon. See Center for Health Care Strategies, Inc., *Comparing State Medicaid Accountable Care Organization Governance Models 2* (July 2015), available at http://www.chcs.org/media/ACO-Governance-Matrix_Final_072415.pdf.

that would include Medicaid beneficiaries as at least one third of the members of the committee. We proposed that the membership include consumer advocates, and be reflective of the demographics of the region covered by the PHP. These entities would be similar to the existing Consumer and Family Advisory Committees (CFACs) that work with the Local Management Entities (LMEs) and would perform some of the same functions, but would have a broader and more diverse membership. We recommended that this council report to the North Carolina Medical Care Advisory Committee on a regular basis. However, the application fails to address this proposal.

Civil Rights Protections

Federal law requires that all Medicaid managed care plans comply with civil rights requirements. Thus, PHPs must obey Section 1557 of the Affordable Care Act, which prohibits discrimination on the ground of race, color, national origin, sex, age, or disability, including sexual orientation. 42 U.S.C. § 12112. They must also ensure that all services are available to enrollees with Limited English Proficiency (LEP), as required by Title VI of the Civil Rights Act. They must ensure that services are provided in the most integrated setting appropriate to an individual's needs, as required by Title II of the Americans with Disabilities Act (ADA) and the Supreme Court's *Olmstead* decision. 42 U.S.C. § 12112. The ADA and *Olmstead* are particularly important. CMS should require strong protections for these services to ensure that participants' civil rights regarding segregation from the community are not violated and the state retains the authority to meet its obligations. This is particularly true, given that the language in the application regarding the incorporation of LTSS, including the NC 1915c waivers for physical disabilities (CAP-C and CAP-DA), is very general. The application mentions none of these requirements, much less explains how NC DHHS will monitor compliance by the PHPs with these laws. CMS should require the state to assure that it will require PHPs to comply with these protections and monitor compliance. Moreover, DHHS should be required to include detailed provisions in the RFPs and, ultimately, the PHPs contracts explaining these requirements, how PHPs will be expected to demonstrate compliance, and how NC DHHS will monitor compliance with these laws.

Medicaid Expansion

While expanding Medicaid eligibility to parents of children in the child welfare system is a positive step to improve health in North Carolina, it is not enough. Accordingly, we urge CMS to strongly encourage North Carolina's leadership to take the opportunity provided by this waiver application to expand Medicaid eligibility as permitted by the Affordable Care Act. Without expansion, hundreds of thousands of adults have no other option for coverage. Moreover, without other access to health care, people turn to the emergency rooms or other safety-net providers. Thus, expanding Medicaid eligibility would greatly reduce the strain on these providers by providing a source of compensation for this care. This in turn will make the new system much more likely to succeed in assuring network adequacy, better health outcomes, and increasing access to early, preventive care, resulting in significant resulting cost savings for the state. Nearly 60% of these uninsured adults are working, but do not have employer sponsored insurance nor can they afford to purchase health insurance. Expansion would enable not only to transform the Medicaid system, but truly transform the lives and health of all North Carolinians.

Thank you for your attention and the opportunity to comment on this application. If you have further questions, please contact Sarah Somers, at (919) 968-6308 ext. 102 or somers@healthlaw.org.

Sincerely,



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