National Association of Public Hospitals and Health Systems

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Dr. Donald Berwick
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Hubert H. Humphrey Building, Room 445–G
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS–2325–P: Medicaid Program; Review and Approval Process for Section 1115 Demonstrations

Dear Dr. Berwick:

The National Association of Public Hospitals and Health Systems (NAPH) appreciates the opportunity to submit comments on the above-captioned Proposed Rule. NAPH supports the goal of the Affordable Care Act and these proposed implementing regulations to improve the process for approving Medicaid and CHIP 1115 waivers by increasing transparency and ensuring that stakeholders—including NAPH members that are critical to providing and often financing the care delivered through waiver programs—have a voice in the process.

NAPH represents approximately 140 metropolitan area safety net hospitals and health systems. These hospitals and health systems are critical sources of care for Medicaid beneficiaries in their communities. In 2008, 27 percent of the inpatient and outpatient services provided by NAPH members were provided for Medicaid patients. Medicaid is the most important source of financing for public hospitals, accounting for 33 percent of total net revenues for NAPH members. In addition, public hospitals provide a substantial portion of care to uninsured patients who may also be impacted by Medicaid waivers. In 2008, 30 percent of outpatient visits and 18 percent of inpatient services were provided to uninsured patients. NAPH members represent only 2 percent of the nation's acute care hospitals, but deliver 19 percent of the uncompensated care. Finally, not only do NAPH members provide Medicaid services, but as governmental entities, many are also often significantly involved in the financing of state Medicaid programs, including state waiver programs, as sources of non-federal share funding.

Section 1115 demonstrations often result in noteworthy substantive and fiscal changes to state Medicaid and CHIP programs. These changes can have significant consequences, both positive and negative, for beneficiaries and the providers that serve them. Demonstrations can also impact public providers in particular to the extent that waivers require or change financing of the non-federal share through public providers or related local government entities. The proposed rule is an important contribution to efforts to enhance transparency and accountability in

government at both the state and federal level. We hope that in the final rule, CMS will continue to strike the right balance in avoiding undue burdens for state and federal officials while improving the ability of consumers and health care providers that are impacted by proposed changes to have a voice in the process.

As CMS finalizes its proposed regulations in an environment where the agency will likely face an increase in waiver activity as implementation of the Affordable Care Act continues to unfold, we ask you to consider the following comments.

1. **The Section 1115 demonstration and review and approval process should explicitly include high-volume Medicaid providers, such as NAPH members, and should provide for a more active role for non-state governmental entities and governmental providers when they are involved in financing a portion of the waiver**.

NAPH strongly supports the opportunity for public notice and comment at the state level and during the federal review process as critical steps to ensure transparency and accountability. Given the significant impact that changes implemented through Section 1115 demonstrations can have on Medicaid providers, CMS should require states to seek input from providers, and particularly safety net hospitals and other high-volume Medicaid providers, as part of the public hearings process. CMS should also consider the impact of waivers on such providers during the federal review process.

Beyond this role in the proposed public comment process, if a state will be relying on non-state governmental entities and governmental providers to finance a portion of a demonstration, it is only appropriate that these entities and providers be afforded a more active role in the negotiation and approval process at both the state and federal levels. At the state level, states should be required to explicitly consult with and hear the comments of these non-state governmental entities and governmental providers prior to submitting the proposal to CMS. This could be accomplished through regulation by, for example, adding a process similar to tribal consultation prior to submission of an application to CMS for review at proposed 42 C.F.R. § 431.408(b). Alternatively, CMS could add an explicit requirement that the state public hearing process at 42 C.F.R. § 431.408(a)(3) must include comments from non-state governmental entities and governmental providers when they will be financing a portion of the waiver. At the federal level, these non-state governmental entities and governmental providers should explicitly have access to CMS to discuss such demonstrations during the federal approval process.

2. **CMS should develop templates to assist states in developing Section 1115 demonstrations to implement voluntary coverage expansions and other programs that serve the goal of reforming the health care system and providing better and more efficient care to Medicaid beneficiaries.**

CMS should support state efforts by providing templates to assist states seeking to design approvable Section 1115 demonstrations to implement important reforms to their Medicaid programs. For example, states may seek to voluntarily expand coverage to childless adults prior to fiscal year 2014, particularly on an incremental or sub-state basis, such as California has done

in its waiver. NAPH member health systems already have programs in place that provide coordinated access to low-income and underserved individuals in their communities—programs that could readily serve as building blocks for such demonstrations. However, it is a significant investment of time and resources for states to pursue such demonstrations, and guidance from CMS to ensure a successful and timely process would be of significant assistance to the states. CMS might similarly consider waiver templates to implement delivery system reforms contemplated under the Affordable Care Act, such as Medicaid accountable care organizations or other efforts to improve care coordination. CMS has done this in the past to support and encourage swift state action. For example, CMS created a model state demonstration application form called "Pharmacy Plus" to allow states to move quickly to expand Medicaid coverage for prescription drugs to Medicare beneficiaries and other individuals with family incomes up to 200 percent of federal poverty guidelines. CMS also created a template application form for the Health Insurance Flexibility and Accountability (HIFA) Section 1115 waiver initiative.

3. CMS should clarify that demonstrations may be terminated only if the state fails to materially comply with the agreed-upon terms and conditions.

NAPH is concerned that the proposed § 431.420(a)(2) would require the Secretary to suspend or terminate beneficial and necessary demonstrations based on non-material defects. The Medicaid statute authorizes the Secretary to suspend federal payments if the State Medicaid Plan has either been changed in a way that renders it non-compliant with Social Security Act or if the administration of the plan substantially fails to comply with any such provision. As the California Association of Public Hospitals and Health Systems (CAPH) notes in its comment letter, NAPH also believes that the Secretary should have similar discretion with respect to demonstrations. The proposed § 431.420(d) provides the Secretary with the discretion to suspend or terminate a demonstration whenever she determines that the state has materially failed to comply with the terms of the demonstration. The discretion afforded by this paragraph is undermined by paragraph (a)(2) of the same section, where the Secretary arguably would be required to terminate or suspend for even the most minor defect. Because subsection (d) provides sufficient authority to allow the Secretary to make terminations and suspensions, NAPH recommends that CMS remove the language regarding terminations and suspensions in subsection (a)(2).

4. CMS should clarify that short-term extensions of an existing demonstration will be permissible, even if initiated less than 12 months prior to the expiration of an existing demonstration.

NAPH believes that the Secretary should be able to grant a short-term extension of an existing demonstration, especially if it is necessary to maintain the stability of a state's Medicaid program. Proposed § 431.412(c) would prohibit the Secretary from considering demonstration extension requests that are not submitted at least 12 months prior to the expiration of the demonstration. NAPH urges CMS to clarify that the Secretary's authority to grant such extensions will be retained under the proposed rule and refers CMS to more a detailed discussion in CAPH's comment letter.

5. **CMS should ensure that the exception to the new federal public notice and approval process at Section 431.416(g) is not overly broad.**

NAPH appreciates that there may be circumstances under which a more expedited review and approval process is necessary. For example, a waiver might be necessary to provide services in the case of a natural disaster or to provide support to the Medicaid delivery system to ensure that critical providers, such as public hospitals, remain in operation. Additionally, in situations where states are seeking a temporary extension of an existing waiver while a successor demonstration is under review, CMS should approve the extension under a more expedited review and approval process to ensure the stability of the Medicaid program. We do not believe, however, that such an exception is an appropriate tool in instances where a waiver would limit the Medicaid program by either restricting eligibility, reducing benefits, increasing cost-sharing for beneficiaries, and/or reducing rates to providers. We recognize the extremely difficult position facing states. However, instances in which waivers propose to limit benefits or eligibility, or to make other changes that will significantly challenge the survival of Medicaid providers, are when full transparency and an opportunity to publicly vet potential consequences are most important.

6. **CMS should post information about recently approved and pending waivers as soon as possible.**

Even prior to these regulations being finalized, it would be helpful for CMS to provide the public with more information on its website about Section 1115 demonstrations that are currently being considered for extensions and new Section 1115 demonstration applications that have been submitted. This transparency will allow Medicaid beneficiaries and providers the opportunity to respond to proposals that may have significant impact, and allow states to learn from what other states are proposing and what CMS is willing to approve. At the moment, it is difficult to obtain consistent and reliable information on the status of pending Section 1115 demonstrations.

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NAPH appreciates CMS' consideration of these comments. Our members are not only critical Medicaid providers but also significantly dependent on and often involved in Medicaid financing. We appreciate your efforts to ensure that NAPH members have a role in the development of significant changes to their state Medicaid programs, as well as CMS' support to state in learning about and pursuing demonstrations that will aid Medicaid beneficiaries and the delivery system that serves them. If you have any questions about these comments, please contact Lynne Fagnani at (202) 585-0100.

Sincerely,

Larry S. Gage
President