July 5, 2011

Dr. Donald Berwick, MD
Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Attention: CMS-2238-P
P.O. Box 8016
Baltimore, MD 21244-8016

Subject: NAMD Comments filed on CMS-2328-P, "Medicaid Program; Methods for Assuring Access to Covered Medicaid Services"

Dear Dr. Berwick:

On behalf of the nation's Medicaid directors, the National Association of Medicaid Directors (NAMD) is submitting comments on the proposed rulemaking entitled, "Medicaid Program: Methods for Assuring Access to Covered Medicaid Services."

On April 4, 2011, NAMD submitted a letter to the Center for Medicaid, CHIP, and Survey & Certification (CMCS) indicating Medicaid directors' request for assistance in two areas: (1) to clarify immediately the CMCS position that states are not required to conduct cost studies before adjusting Medicaid rates nor must their rates be cost-related; and (2) to issue proposed regulations relating to provider reimbursement that give states appropriate flexibility in applying statutory criteria governing payment rates. CMCS then issued its proposed rule (CMS-2328-P) selectively elevating an access standard that would constrain the states' ability to use a balanced approach to meet all of Congress' requirements. On June 7, 2011, NAMD submitted a preliminary communication to CMCS indicating Medicaid directors' overarching concerns with the approach of the proposed regulation (CMS-2328-P) and the additional administrative pressures it will impose on all states.

Medicaid directors agree that access is an important component when considering the 42 U.S.C. 1396a(a)(30)(A) statutory requirements, but the statute also requires assurances of economy, efficiency and appropriate utilization. States understand the complexity of trying to balance such requirements in the delivery of health care services. However, we

remain concerned with the potential impact of specific provisions included in the proposed rule.

Medicaid directors are committed to developing reasonable solutions on these and other provisions of the proposed regulation. Therefore, we respectfully request CMS withdraw the proposed regulation and engage in additional dialogue with Medicaid directors. Should CMS choose to move forward, we urge the agency to amend the regulation to reflect the recommendations and requests for clarity contained in this letter.

Summary of Recommendations

- NAMD recommends changes to the review and monitoring requirements of the proposed rule. For example, states would periodically review and monitor access. States would determine the measures of access and beneficiary information included in such reviews. This would allow states to take a more balanced approach to evaluating access.
- State Medicaid directors share the goal of ensuring enrollees have sufficient access to services. NAMD recommends changes to the rule such that, if and when access issues are found, a state would develop and implement its own corrective action plan. States would maintain ongoing mechanisms for obtaining beneficiary input, for example using hotlines, surveys, and other tools.
- Advance review of rate reductions would place an unreasonable burden of proof on states and create an overly bureaucratic process that will impede the timely and efficient operation of state Medicaid programs. NAMD recommends that, when a state is proposing rate reductions or restructuring that could result in access issues, the state must submit the most recent access review. In addition, the state would develop procedures for monitoring access to care *after* implementation of the rate change.
- The position of the Solicitor General of the United States, as conveyed in his December 2010 filing in the case of *Independent Living Center v. Maxwell-Jolly,* is that cost studies are not required. The proposed rule lacks a similarly clear statement. Our Association urges CMS to clearly affirm that cost studies are optional, *not* required, and there is no requirement to reimburse providers at cost. Further, the rule should be revised to permit states to take into account available resources or other factors in setting rates.

Comments

Clarification of references to cost based studies

The proposed rulemaking conflicts with the position of the Solicitor General which advised that 42 U.S.C. 1396a(a)(30)(A) imposes *no* obligation on states to consider cost studies to ensure that payment rates bear a reasonable relationship to provider costs. In a brief responding to the ruling of the Ninth Circuit Court of Appeals, the Solicitor General stated that:

> "[t]here is no general mandate under Medicaid to reimburse providers for all or substantially all of their costs, and Section 1396a(a)(30)(A) does not set forth any requirement that a State consider cost studies in setting payment rates….there is no requirement that Medicaid assume all or substantially all of the costs incurred by providers in order to ensure reasonable access to quality care."
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> *Maxwell-Jolly v. Independent Living Centers of California* 572 F.3d 644 (9th Cir. 2009).

As currently drafted, the text of the rule implies, and the Preamble emphasizes, that there may be circumstances where cost studies are in fact required. For example, the Preamble language about cost studies reads, "cost may be one consideration affecting access to care" and that it is "not particularly productive to rely solely on [cost] as a measure of access."

Therefore, we request that CMS explicitly state in the final rule that cost studies and cost-related studies are not required. We ask that CMS clearly affirm the position of the Solicitor General's December 2010 filing in the case of *Independent Living Center v. Maxwell-Jolly*.

In addition, we recommend that the agency clearly explain in the rule that 42 U.S.C. 1396a(a)(30)(A) also embodies a strong policy against over-utilization of medical services, and that it is both appropriate and desirable that states adopt rate policies that will discourage unnecessary utilization of services and embody incentives for more efficient use of health care resources.

447.203 Documentation of access to care and service payment rates

Medicaid directors understand CMS's desire to ensure sufficient access to care for Medicaid beneficiaries. State Medicaid directors share this goal and seek to comply with this in the context of other Medicaid statutory requirements. The Discussion section of the Preamble affirms that states use a broad range of tools and resources to establish service delivery systems for covered health care items and services, to design the procedures for enrolling providers of such care, and to set the methods for establishing provider payment rates. Specifically, page 26343 reads as follows:

> "[A State plan for medical assistance must] provide such methods and procedures relating to the utilization of, and the payment for, care and services available under the plan (including but not limited to utilization review plans as provided for in section 1396b (i)(4) of this title) as may be necessary to safeguard against unnecessary utilization of such care and services and to assure that payments are consistent with efficiency, economy, and quality of care and are sufficient to enlist enough providers so that care and services are available under the plan at least to the extent that such care and services are available to the general population in the geographic area".

We are concerned that the proposed revisions to the rule are inconsistent with the 42 U.S.C. 1396a(a)(30)(A) as cited in the Discussion section referenced above. States are responsible for ensuring efficiency, economy, quality of care, and access, which is a much broader responsibility than simply the sufficiency of payment rates. Payments must satisfy three functions:

1) Payments need to be low enough to safeguard against unnecessary utilization;

2) Payments need to be in amounts that ensure efficiency, economy, and quality of care; and

3) Payments need to be sufficient to enlist enough providers so that plan services are available to Medicaid enrollees in the same amount as are available to the general population in the geographic area.

The proposed revisions at Section 447.203(b) would require state Medicaid agencies to demonstrate access to care. We believe this does not provide a reasonable approach for states to incorporate all of these objectives into rate development and compliance considerations. Further, the provisions of the regulation are overly prescriptive and do not explicitly give a state discretion for how to make such determinations about access.

Instead, we believe the actual wording of the regulation imposes extraordinarily burdensome requirements for measuring access that could overwhelm states in legal challenges and stymie reasonable and necessary changes to the Medicaid program.

Similarly, the proposed revisions to the regulation impose very explicit and extensive minimum requirements for the access reviews that we believe some courts will interpret as *requiring* cost studies.

We request that CMS reevaluate these requirements given that states have extensive experience, account for numerous factors (including, but not limited to, access), and use a wide range of tools to ensure that they set rates sufficient to retain providers in their systems. As written, the proposed rule threatens to undermine states' expertise and a balanced approach to rate setting. Our comments in the next section discuss an approach that would allow states to take a more a balanced approach to evaluating access.

447.203(b) Access review data requirements

The proposed revisions at 447.203(b) state, "The agency must record and update, medical assistance access reviews for each covered benefit, in accordance with timeline describe in paragraph (c) of this section…" This section also requires states document in their access review "an analysis that demonstrates sufficient access to care…"

We recommend that the agency revise this language to make it consistent with the Preamble language that explains states would need to "consider" the access impact and commit to ongoing monitoring *when appropriate*. The language as currently drafted is problematic in that states cannot reasonably be expected to predict how access will be impacted by any one particular change.

In addition, the proposed revisions require state reviews include specific data on Medicaid payment levels, including (1) Medicaid rates as a percentage of average customary provider charges; (2) Medicaid rates as a percentage of Medicare rates, average commercial payer rates, or the applicable Medicaid allowable cost of the service; and (3) an estimate of the average percentage increase or decrease resulting from any proposed change in payment rates. We are concerned that the requirement for such market rate comparisons does not reflect Medicaid agencies' experience with market forces and what is needed for prudent purchasing of services. For example, the market may continue to supply willing providers at a lower cost relative to other payors. Therefore, simply comparing Medicare and commercial to Medicaid and citing lower Medicaid rates is an inadequate approach that will not lead to an accurate comparison. Other factors drive differences in rates in some markets. In addition, some state Medicaid programs are unable to obtain access to commercial rates because this information is considered proprietary.

Further, we believe the text of the revised regulation incorrectly assumes that the term "general population," as it is found in 42 U.S.C. 1396a(a)(30)(A), is a fully insured population with 100 percent access to care. None of the examples of reference groups

provided (e.g., Medicare and the commercially insured populations) are as broad as the general population. The general population includes Medicaid recipients themselves *and* those who are uninsured. We also believe that the comparison of access to plan services for Medicaid consumers versus private pay services for non-Medicaid enrollees is an incorrect interpretation of the statute.

Our Association recommends revising the proposed regulation to reflect that the statute's requirement on access to care is a relative standard, meaning that Medicaid should not be held to a higher standard for access than that for the general public. For example, we ask the agency to list population-based access standards as an explicitly acceptable point of reference for comparing access to services between the Medicaid population and the general population. We also recommend that the rule indicate that states may consider adjusting access standards to take account of the independent effect of socioeconomic status and other factors when comparing to commercially insured populations. In general, we ask the agency to reconsider the language in this section to ensure it does not place the entirety of responsibility on Medicaid for resolving access differences.

The proposed revisions in this section also require a stratified array of "access review data." Section V of the Preamble describes this requirement and concludes that "presenting the data in this manner should inform states as to whether payments are consistent with efficiency, economy, and quality and [sufficient access]." We are concerned that this implies that state demonstration of beneficiary access is (a) the only necessary criteria for approval of state payment rates, and (b) sufficient to demonstrate broad compliance with the requirements of 42 U.S.C. 1396(a)(30)(A).

Our Association requests that the agency reevaluate the extensive requirements and specific list of items and analysis that state Medicaid agencies must include in their reviews. We recommend that states be allowed to determine the access measures that are meaningful for their specific circumstances. Further, we recommend that such revisions be structured to ease the administrative burden otherwise imposed by the current proposed revisions. This would allow states to take a more a balanced approach to evaluating access.

As currently written, it is unclear what, if any, standard or criteria CMS would apply to evaluate such data and what the agency would consider to be an access issue. For example, if there is an intervention on the part of the state to assist in arranging for a service, would this be considered an access problem that triggers corrective action plan? If it requires a few days for the state to arrange service, would this be considered an access problem? Should CMS proceed with the regulation as drafted, states request clarification as to how the agency will evaluate the data from access reviews. States also

seek clarification as to how CMS would apply or evaluate the data when deciding to approve or disapprove a state plan amendment.

447.203(b)(2) Access review timeframe

The proposed revisions to 447.203(b)(2) require states to complete the access review for all covered services at least once every five years. Currently, states employ a range of approaches for monitoring access. Therefore, we are concerned that the proposed review schedule is overly proscriptive and adds an unnecessary layer of administrative burden – even with the option for states to determine the detailed review schedule. Further, the mandatory review of *all* services, regardless of past experience or any other factors impacting access, places undue pressure on state resources, particularly during this period of already stressed Medicaid budgets.

NAMD requests that the agency work with states to diminish the overly-prescriptive aspects of the regulation and develop a more balanced and targeted approach for addressing areas of concern with access, as defined and identified per our recommendations in the previous subsection.

447.203(b)(3) Special provisions for proposed provider rate reductions or restructuring

The proposed revisions in 447.203(b)(3) require states to conduct access reviews to prove *in advance* that there will be no adverse effect on access. We believe this section creates a stricter standard than that proposed in revised section 447.204 and could be interpreted to mean that states must demonstrate in advance of submission that rate reduction or restructuring will not adversely impact access.

Advance review of rate reductions would place an unreasonable burden of proof on states and create an overly bureaucratic process that will impede the timely and efficient operation of state Medicaid programs. Based on states' experience, we believe the extensive and specific nature of the advance review requirement will result in less, rather than more, flexibility for states. Further, the rule conflicts with state legislative and budgetary cycles and will prevent states from making timely adjustments to rates.

In addition, we are concerned that this front end access review closely resembles the "finding" requirement that was at the heart of the "Boren Amendment," which gave rise to enormous cost concerns and legal challenges that eventually led to its repeal. Similarly, we believe the proposed regulation would create an unworkable standard for states to meet and is likely to overwhelm states with legal challenges.

NAMD urges CMS to adopt the approach contained in the "Monitoring Procedures" section as a model for addressing our concerns with the more prescriptive provisions of

the rule. Specifically, when a state is proposing rate reductions or restructuring that could result in access issues, the state would submit the most recent access review, consistent with our recommended changes to the reviews included in the previous subsection. In addition, the state would be required to develop procedures for monitoring access to care after implementation of the rate change. The state would be responsible for defining the monitoring plan in such situations.

447.203 (b)(3) Threshold for payment changes: CMS requested comments on whether the agency should more clearly define "significant" change in payment policy or eliminate "significant." Under the current policy, all changes in payment policy are considered "significant." States believe this policy is unreasonable and impedes the efficient operation of a state Medicaid program.

If CMS proceeds with the proposed change to require advance approval of rate changes as drafted, our Association recommends that the agency convene a workgroup with state Medicaid agencies to develop thresholds. States would retain authority to make payment rate changes without first obtaining CMS approval within this agreed upon threshold. We also recommend that CMS consider different standards for different services. For example, standards could vary based on whether services were optional or mandatory.

447.204(b)(4) Mechanisms for ongoing input

The proposed revisions in 447.204 (b)(4) require states to implement ongoing mechanisms that allow beneficiary feedback. We are concerned that as proposed the text lacks a threshold requirement to determine when such a process would be required. Requiring states to implement an ongoing input process for every change, regardless of the scope, creates a significant administrative burden for states. This would be an inefficient use of limited resources in situations where states are making minor changes.

We request that CMS work with states to define a threshold that would trigger the need for beneficiary input. We recommend that CMS adopt language for such a process similar to that contained in the proposed "Monitoring Access" provisions whereby the state is able to define the procedures and process.

447.205(b)(5) Addressing access questions and remediation of access issues

The revisions to the proposed text in 447.205(b)(5) would require states to have a corrective action plan that remediates any identified access problem within 12 months. The language requires states to develop a corrective action plan regardless of whether any identified access issues would indicate non-compliance with the statutory standard.

We ask CMS to work with states to reduce the additional administrative burden this requirement newly imposes on states. Specifically, states should develop their own corrective action plan if access issues are identified in the periodic reviews or based on beneficiary input, according to our recommendations. Again, states share the goal of ensuring enrollees have sufficient access to services. If access issues are identified, states work to resolve these in a timely manner. However, there are several situations for which the proposed timeframe is likely to be unrealistic.

Further, the proposed timeframe does not consider the complexity of factors – beyond provider payment rates – that can give rise to an access deficiency or rate change. For example, even in situations where a rate increase is not required to resolve an access problem, the corrective action plan may involve additional expenditures to modify state systems and meet additional administrative costs. In some states these funds may not be included in the state general fund appropriation provided by the state legislature for that state fiscal year. In addition, state legislation may require a short time frame for implementation of payment rate increases or decreases. Lengthy policy conversations about access and studies and reviews will impede states' ability to make changes in a timely manner.

We urge the agency to modify the rule to reflect a timeline that considers constraints on state agencies stemming from state legislative mandates to implement changes or when they otherwise need legislative approval for funding to implement the proposals contained in a corrective action plan. Further, if the requirements are implemented as proposed, we ask you to amend the rule to include timelines that accommodate states that have biennial legislative sessions.

In addition, the proposed corrective action plan and remediation timeline do not recognize that some states are, in whole or in part, designated as Health Professional Shortage Areas or Medically Underserved Areas. We request that the agency amend the rule to recognize the exceptional difficulty associated with increasing access in such regions within a 12 month period.

Additional Comments

In addition to comments on specific sections, NAMD has the following concerns and requests.

Information Collection Requests and Regulatory Impact

We believe the various new information collection requests (ICRs) and the estimated regulatory impact of the proposed rule are grossly understated. The rule mandates states collect and review data analyzing access to care consistent with the framework proposed in the March 2011 report of the Medicaid and CHIP Payment and Access Commission (MACPAC). States must perform access reviews for a subset of services each calendar year and release results through public records or a website each calendar year. The review process also requires states solicit input from beneficiaries.

While many states may currently include *some* of these processes, most states will have to make significant policy and operational changes with a cost that will be many times larger than that estimated in the rule. For example, section 447.203 proposes to require that a state record and update medical assistance access reviews for *each covered benefit*.

We are concerned about the broad scope of this language and the new, substantial administrative burden this will impose on states. We maintain these concerns irrespective of the overall state fiscal situation. The already stressed condition of many state budgets only serves to make the review and documentation mandates more troublesome and onerous to meet, in turn forcing state to reprioritize their resources**.** NAMD strongly recommends that CMS revisit these estimates and seek state input to more accurately determine the additional resources that would be needed to comply.

Payment versus Rates

Although states and CMS commonly refer to "payments" and "rates" interchangeably, they are substantively different. The Eighth Circuit has ruled that the word "payments" encompasses much more than rates and includes any change to a Medicaid program that has the potential of affecting provider revenues. This can effectively prohibit states from making any changes to the Medicaid program, and is clearly not the intent of the statute. The proposed regulation could resolve this confusion by declaring that "payments" as used in 42 U.S.C. 1396a(a)(30)(A) refers to the specific payment rates for reimbursable medical assistance furnished under the state plan or waiver.

MACPAC framework for measuring access

In establishing various procedural requirements for tests of ongoing sufficient access, CMS further reinforces the pre-eminence of the access provision over the other three Congressional requirements for Medicaid payment rates. Use of MACPAC's three-part framework reinforces this imbalance. This initial framework was not intended for use in this context and it does not attempt to balance the other requirements of efficiency, economy and quality of service. We also believe it is flawed to rely on MACPAC's framework because, as stated in the entity's March 2011 report, the framework is a

starting point that Commissioners anticipate will evolve over time. It is not a "recommendation" as characterized by CMS.

On behalf of NAMD, we thank you for the opportunity to comment on this proposed rule. We are committed to continuing to work with CMS on these issues as the rulemaking process moves forward. If you have any questions or concerns about these submitted comments, please do not hesitate to contact Andrea Maresca, NAMD's Director of Federal Policy and Strategy at andrea.maresca@namd.us.org.

Sincerely,

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