NATIONAL ASSOCIATION OF PSYCHIATRIC HEALTH SYSTEMS
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July 3, 2013

Ms. Marilyn Tavenner, Administrator
Centers for Medicare and Medicaid Services
U.S. Department of Health and Human Services
Room 445-G, Hubert H. Humphrey Building
200 Independence Avenue, SW
Washington, DC 20201

RE: CMS–3255–P: "Medicare and Medicaid Programs; Survey, Certification and Enforcement Procedures" (42 CFR Parts 488 and 489)

Dear Ms. Tavenner,

As an association representing behavioral healthcare provider organizations and professionals, the National Association of Psychiatric Health Systems (NAPHS) appreciates the opportunity to provide comments on the proposed rule (CMS-3255-P) titled "Medicare and Medicaid Programs; Survey, Certification and Enforcement Procedures" as originally published in the April 5, 2013, *Federal Register* (with a subsequently extended comment period as published in the May 24, 2013, *Federal Register*).

Founded in 1933, NAPHS advocates for behavioral health and represents provider systems that are committed to the delivery of responsive, accountable, and clinically effective prevention, treatment, and care for children, adolescents, adults, and older adults with mental and substance use disorders. Our members are behavioral healthcare provider organizations, including more than 700 psychiatric hospitals, addiction treatment facilities, general hospital psychiatric and addiction treatment units, residential treatment centers, youth services organizations, outpatient networks, and other providers of care. Our members deliver all levels of care, including inpatient care, residential treatment, partial hospitalization, and outpatient services.

COMMENTS

NAPHS and its members have a significant history of working with both the Hospital Conditions of Participation and the Special Conditions of Participation applying to psychiatric hospitals. Our members are predominantly accredited by The Joint Commission (TJC) Hospital Accreditation Program (which now includes deemed status for the special conditions for psychiatric hospitals). We appreciate the collaborative relationship between these two entities, and feel their challenging work together has, on the whole, produced a survey process that advances the goals of high-quality and safe care that serve Medicare beneficiaries well.

However, we write to express our concern about the April 5, 2013, proposed rule regarding survey, certification, and enforcement procedures. We feel the requirements of this proposed rule are not in the best interest of Medicare and Medicaid beneficiaries and add significant burden to the providers who care for them by creating duplicative and outmoded requirements.

ACCREDITATION STANDARDS AND ALIGNMENT WITH CONDITIONS OF PARTICIPATION

We read the proposed rule as greatly increasing the prescriptive oversight by the Centers for Medicare and Medicaid Services (CMS) of the accrediting organizations that have or are requesting deemed status. The reason given in the proposed rule to justify this increased oversight is a series of articles and reports dating from 2005 and before (p. 20565). In a public-private partnership that, from our perspective as providers, has been functioning ever-more effectively regarding alignment with the Conditions of Participation (CoPs), rigor of survey process, integration of accreditation requirements, and review of areas of concern, we think TJC and CMS have heeded the recommendation of the Office of Inspector General (OIG) and done their work well. We see no need for the more prescriptive alignment between the CoPs and standards of accreditation organizations. We fear the detailed analysis you are suggesting would involve comparing (perhaps "matching") accrediting organization standards to the State Operations Manual (SOM) in order to determine substantial compliance. The SOM is sub-regulatory; has not been revised, in many cases, for a very long time; is subject to change at any time; and is without formal government or public review. It gives guidance to state surveyors, but does not hold regulatory weight. We support the existing phrase "taken as a whole" to be the standard by which AOs be required to demonstrate that their standards meet or exceed Medicare requirements and not alignment with the SOM.

APPROVAL IN ENTIRETY OF ACCREDITATION PROGRAM

The proposed rule adds a new provision (488.4(b)) that would require that an accrediting organization's CMS-approved accreditation program be approved in its entirety This appears to go beyond the intent of deemed status and the regulatory authority of CMS. Accrediting organizations can develop requirements that provider organizations voluntarily agree to meet as a value-added benefit of accreditation. This has nothing to do with the deeming process. We believe the only elements that should be considered in the deeming application are the same elements that are considered by state surveyors as they conduct the survey required for deemed status under Medicare. We repeat that substantial compliance should be determined by reviewing the AOs standards "taken as a whole." The SOM is guidance for state surveyors and should not be used as the basis by which AOs' standards or survey processes be judged.

PROTECTED WORK PRODUCTS

In 488.5(a)(4)(viii) CMS proposes that AOs must agree to "provide CMS with a copy of the most recent accreditation survey for a specified provider, together with any other information related to the survey as CMS may require." From the provider prospective, we ask for clarification that the information required would only be related to the deemed status accreditation survey. We are concerned that certain information is protected from disclosure by federal standards and would lose protected status if shared with CMS.

COMPOSITION OF SURVEY TEAM

We are concerned about proposed 488.5(a)(6), which requires the AO to furnish CMS with the "criteria for determining the size and composition of the organization's survey teams for its survey teams…" This opens the door to CMS mandating a certain number and type of surveyors. While we agree that a uniform size survey team would not be appropriate, our consistent experience with The Joint Commission is that they adjust the size and composition of the team to meet the complexity of the organization. We know from experience that state and CMS teams are often large and may stay for many days. There are no criteria available to the organization being surveyed about the reasons for the size or composition of the state or CMS team. Provider organizations pay a lot of money per survey day to AOs. If CMS mandated a size or composition for AO teams which mirrored their own teams, it would have a very direct impact on the cost of the deeming process for organizations because we would still be required by our AO to pay per surveyor day.

NOTIFICATION OF AO'S CMS-APPROVED ACCREDITATION REQUIREMENTS

At 488.5(a)(19),CMS proposes that accrediting organizations provide written notification at least 60 days in advance of any proposed changes in the organization's CMS-approved accreditation program

requirements and agree to not implement the changes before receiving CMS approval. With the high degree of oversight proposed throughout this document, we are concerned that approval might extend to non-deeming aspects of the AOs standards. NAPHS has been involved with the standards development, adoption, and implementation process of the Joint Commission for many years. There have been times when it was imperative to move the standards development process quickly to address critical issues in the field. In reading the proposed rule, it could be inferred that CMS could potentially have influence over the AOs' internal processes (with power to approve or disapprove standards or survey decisions) in areas that do not relate to the Medicare program. NAPHS strongly opposes this provision of the proposed rule.

CMS DETERMINATION OF PROVIDER COMPLIANCE WITH CoPs BASED ON AO'S SURVEY REPORT

At 488.7(a), CMS would be allowed to determine that a provider does not meet the applicable Medicare CoPs "based on its own investigation of the accreditation survey or any other information related to the survey." As providers, we are very concerned that an arbitrary review of an AO's survey report be used as the basis for a deeming decision. Would there be criteria for such a review? Who at CMS would be qualified to do the review? Would this be done at the state, regional office, or central office level? Would there be communication between CMS and the AO? Our experience is that there is already in place a rigorous process for determining compliance with the CoPs and that adoption of this proposed provision would put providers at great and unnecessary risk. CMS always retains the right to survey an organization about which there is a compliance question. That survey should be the basis for a CMS decision if there is a difference of opinion between CMS and the AO .

VALIDATION PROCESS

Throughout the proposed rule there are references to the survey validation process (both routine validations and complaint). This is an area that needs much review and discussion by all affected parties. The current process sets up a potentially adversarial relationship among the provider organizations, CMS, and the accrediting organizations. We hear many comments about state agency surveyors explaining their purpose is to find problems the AO missed. There is wide variation in the survey style and emphasis of state surveyors. In an environment of shrinking state resources, they are often surveying areas that are not their areas of expertise. The criteria for conducting a validation survey in the proposed rule (non-compliance) are not consistent with the regulatory text, which references "significant deficiencies that adversely affect health and safety of patients". The number of complaint surveys is greatly out of proportion to the number of condition-level deficiencies or immediate-jeopardy situations that are uncovered during these surveys. The waste of resources and upheaval this brings to the field are huge problems. The validation process is flawed and cannot be fixed by the changes outlined in the proposed rule. We are concerned that the heightened levels of oversight will only exacerbate the situation. Very significant resources are expended by all parties (most importantly, from our perspective, by the provider organizations) for a process that has virtually no value added and creates significant angst. We suggest a high-level reconstruction of the validation process with significant input from all parties affected.

IMPORTANCE OF A COST-EFFECTIVE DEEMING PROCESS

Providers must be mindful of cost, and every new requirement listed in this proposed rule will generate costs that the AOs will potentially pass on to providers. We think both states and providers have demonstrated a high level of commitment to the deeming process which, hopefully, no one wants to see undone. State budgets have been designed with AOs assuming major responsibility for performing deemed status surveys. We had a great deal of experience until very recently with having to depend on state surveyors to assess the psychiatric special conditions. States regularly said they did not have the resources to perform these surveys, in spite of the support of the federal panel (whose budget has consistently been eroded over the years). Facilities that were clearly needed in their communities might wait in excess of a year before being surveyed for Medicare and Medicaid—making the facilities unavailable to beneficiaries. Deemed status for the psychiatric special conditions has almost eliminated this bottleneck as well as eliminated the tremendous surveyor variability experienced among the states.

In reading through the proposed rule, it is clear that CMS has much flexibility and judgment regarding how it constructs the deemed status process. However, one is struck with the weight of the burden being

placed on the accrediting organization with little rationale or apparent statutory authority. We would hate to see an enforcement/oversight process within CMS that would monitor AOs in a way that is far out of proportion to the concerns that have ever been raised about the sufficiency of the existing deeming process. Costs for this oversight and response will be doubly borne by providers through taxes and through the cost of accreditation. In an era of significant concern about regulatory burden, this is an important issue to examine.

We have watched the deeming process evolve over the last several years. The original partnership among all parties, which was intended to lead to a continuous monitoring of the quality of care delivered to Medicare and Medicaid beneficiaries, has, at times, become an overly complex and even adversarial process. Providers are left to deal with (and pay for) the consequences of a duplicative, archaic, and fractured process. We are very concerned that changes in regulatory requirements could come at any time (on no particular schedule), leaving us with little time to assure implementation, and increasing our risk for noncompliance.

NAPHS suggests a reimagining of the role of deeming within the accreditation process in which all parties bring their strengths to the table in the service of a process that is based on trust, professional judgment and oversight, the most current approaches to quality of care, and the best interests of Medicare and Medicaid beneficiaries. We stand ready to participate in that discussion from the invaluable perspective of the provider community. Imposition of many of the elements of the proposed rule is not the way to achieve the aims of safe care, improving the experience of care, and increasing cost effectiveness.

We support the deemed status process; however, given the extent of problems we see, we recommend that this proposed rule be withdrawn as currently written.

CONCLUSION

Thank you for your consideration of our comments. We look forward to working with CMS and the Department of Health and Human Services to ensure that Medicare and Medicaid regulations continue to provide beneficiaries with access to high-quality behavioral health services.

Sincerely,

/s/

Mark Covall
President/CEO