



March 18, 2011

Donald Berwick, M.D.
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-2400-P: Medicaid Program; Payment Adjustment for Provider-Preventable Conditions Including Health Care-Acquired Conditions

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 represents more than 140 metropolitan area safety net hospitals and health systems that share the common mission of providing safe, high quality health care to all patients regardless of ability to pay. These hospitals and health systems are critical sources of care for low-income and vulnerable patients in their communities—about half of all the care provided by NAPH members is for Medicaid and uninsured patients. NAPH members provide 20 percent of all hospital compensated care. Medicaid continues to be the most important source of revenue for public hospitals, accounting for 35 percent of NAPH members' total net revenues. Our members are also critical to the training of future health professionals; fully a quarter of all physicians in our nation train at NAPH member sites.

NAPH and its members are committed to the goal of improving safety and quality of care for Medicaid patients that Congress sought to promote through Section 2702 of the Affordable Care Act ("ACA") by prohibiting Medicaid payments for health care-acquired conditions ("HCACs"). NAPH has collaborated with the National Patient Safety Foundation ("NPSF") to bring patient safety education and training initiatives to our members through The Patient Safety Initiative at America's Public Hospitals. Launched in October 2009, the initiative provides tools, resources, and educational opportunities to support and grow critical patient safety activities. The Initiative's goals are to:

- position public hospitals on the leading edge of patient safety and quality care;

- establish a consistent and shared pool of patient safety knowledge, tool sets, and techniques;
- develop a community of public hospital clinicians, patient safety and quality leaders, and hospital executives committed to this initiative;
- garner measurable results in patient safety practices; and,
- create patient and community programs fostering communication that engages, informs, and builds continued confidence in care and the public hospital system.¹

We encourage CMS to look to our members' recent initiatives to enhance patient safety—for example, the development and testing of a patient-friendly daily medication schedule that includes patients as partners in their hospital care, or a multidisciplinary approach to falls prevention that involves all members of the health care team, as well as patients and families—and their remarkable results.² NAPH members have undertaken efforts to improve physician alignment and to engage the hospital leadership—almost 90 percent of NAPH members share quality performance data with their physicians and 80 percent engage their boards of directors in quality improvement activities. Through these efforts, NAPH members have been able to effectively improve the health of the most vulnerable patients in their communities.

NAPH and its members look forward to working with CMS and the states to implement the payment changes for HCACs mandated by the ACA in a way that is most likely to improve patient safety and quality of care. We hope that prior to issuance of a Final Rule and throughout program implementation, CMS will engage in further discussion with the provider community about the issues identified below to ensure that the program is achieving the intended goal. Medicaid HCAC policies should meet the following principles:

- Address the patient safety issues of most concern for the Medicaid program
- Be limited to conditions for which there is clear scientific evidence and practical experience demonstrating that the HCAC is reasonably preventable, taking into account that safety net providers often treat vulnerable patients with multiple comorbidities
- Be limited to conditions for which there is clear scientific evidence and practical experience demonstrating that the HCAC is reasonably detectable, taking into account that safety net providers often treat vulnerable patients with multiple comorbidities
- Include only conditions researched and vetted by experts, including the provider community
- Not reduce access by discouraging hospitals from taking the highest risk patients or penalize the safety net hospitals that, by their missions, are dedicated to treating those patients
- Be driven by patient safety and not a quest for cost savings

CMS should ensure that these principles are met prior to encouraging or approving expansion of non-payment provisions in the Medicaid program. NAPH is concerned that rapid expansion of Medicaid HCAC policy to conditions and settings beyond CMS' experience under the current

¹ See <http://www.naph.org/Main-Menu-Category/Our-Work/Quality-Overview/Patient-Safety-Initiative.aspx>.

² See <http://www.naph.org/Homepage-Sections/Explore/Innovations/Patient-Safety-Innovations.aspx>.

Medicare hospital-acquired conditions (“HAC”) program could inappropriately penalize hospitals for conditions that were not acquired in the hospital or could not have been prevented. NAPH members treat a significant number of high risk patients who are particularly vulnerable to complicating conditions, both preventable and not. A policy that limits payments to providers for conditions that are not preventable by a provider, or cannot reasonably be identified by a hospital provider on admission, will disproportionately and inappropriately penalize our members. We urge CMS to limit this policy to those conditions for which there is clear scientific evidence and practical experience demonstrating that the HCAC is both preventable by the provider and reasonably identifiable. Otherwise, safety net providers may lose payment on a significant number of high risk patients without improving quality—even more so when Medicaid expands in 2014 and absorbs potentially even more vulnerable, previously uninsured, patients. These providers are, and will continue to be, critical to providing access to care for Medicaid patients, and are often the only source of such access.

NAPH highlights the following aspects of the Proposed Rule as areas where more consideration is necessary so that the Medicaid HAC program can achieve the goal of raising the overall quality of care in the current health care system.

1. CMS should initially limit the scope of the Medicaid nonpayment program to those HACs identified in the Medicare nonpayment program, to the extent appropriate for Medicaid, and to the inpatient acute care setting to which the Medicare program applies.

CMS proposes to prohibit payment not only for conditions identified in the Medicare HAC program, but also for any additional HCACs and other provider-preventable conditions (“PPC”) in “any health care setting” identified by the states.³ We recognize that states are valuable partners in identifying patient safety issues, but CMS should also incorporate the lessons learned from the Medicare HAC program regarding the importance of appropriately vetting proposed HCACs with its agency partners, with other expert organizations, and with the public.

The Medicare HACs have gone through a significant vetting process, involving the Centers for Disease Control and Prevention (“CDC”) and the Agency for Healthcare Research and Quality (“AHRQ”), testing sessions with the public, meetings with associations, and comment periods outside of regulatory issuances. CMS acknowledges in the preamble to the rule that “Many states that have implemented HCAC-related policies have adhered to Medicare because the conditions have been researched and are generally accepted by the provider community.”⁴ We question whether there would be sufficient time for CMS to perform a similarly rigorous process in reviewing state-proposed preventable conditions prior to the September 30, 2011 deadline by which state plan amendments (“SPAs”) must be approved. Many states simply are not capable of doing a similarly intensive review on their own, so federal guidance is necessary.

³ Proposed 42 C.F.R. § 447.26.

⁴ 76 Fed. Reg. 9283, 9289 (Feb. 17, 2011).

CMS should not encourage states to expand beyond the scope of the Medicare HACs and the inpatient setting until there is more time for study and vetting. In fact, Congress recognized in the ACA that more study is required before the existing *Medicare* HAC program can expand to other settings beyond inpatient acute care hospitals (such as inpatient rehabilitation facilities, long-term care hospitals, hospital outpatient departments, and other hospitals excluded from the inpatient prospective payment system, skilled nursing facilities, ambulatory surgical centers, and health clinics).⁵ Congress specifically directed CMS to analyze “how such policies could impact quality of patient care, patient safety, and spending under the Medicare program” prior to making any recommendations for legislative or administrative action. If the Medicare program is only studying expanding to other settings and has already had experience with implementing non-payment for HACs, it suggests that a more incremental approach similarly would also be appropriate for Medicaid. Other settings, such as rehabilitation and psychiatric hospitals, involve particularly challenging and complex patient populations and HCAC policy may need to be more specifically tailored for such settings.

We understand that Congress directed CMS to identify current state practices that prohibit payment for HCACs, and value the work that CMS has started of reviewing these practices. CMS review can help identify HCAC-related payment provisions that are inconsistent or not supported by clear scientific evidence, and conversely can help identify and disseminate practical state experiences with HCACs for which there is clear scientific evidence and which are preventable and reasonably identifiable. However, CMS admits that the process of collecting this information from states is not yet complete. The survey instrument is still voluntary and is undergoing review under the Paperwork Reduction Act, so only a few states have provided information.⁶ CMS should review the full results of these surveys and use that information to inform policy around HCACs that are appropriate for the Medicaid program and have an evidentiary basis for successfully improving safety and quality—prior to encouraging states to expand their Medicaid HCAC programs beyond the scope of Medicare. Even with the information already gathered, CMS admits in the preamble that there is inconsistency in describing conditions across states and that some states lack the data necessary to identify HCACs and related quality issues.⁷

Limiting the proposal to Medicare HACs, at least initially, is more consistent with the language of Section 2702. Congress uses the term “health care-acquired conditions,” which it defines based on the Medicare statutory definition for the Medicare HAC program (SSA Section 1886(d)(4)(D)(iv)). The Medicare program is limited to hospitals paid under the Medicare inpatient prospective payment system, suggesting that Congress envisioned a Medicaid policy that similarly applies only to subsection (d) hospitals. Furthermore, the requirement that CMS “incorporate the [state] practices identified, or elements of such practices, which the Secretary determines appropriate” suggests that CMS would be suggesting particular HCACs to add to the list of Medicare HACs for purposes of the Medicaid program, not that CMS would leave complete flexibility to the states to identify and define HCACs in potentially varied and inconsistent ways across Medicaid programs.

⁵ ACA § 3008(b).

⁶ *Id.* at 9287.

⁷ *Id.* at 9287, 9290.

2. CMS should implement a rigorous review process, like that in Medicare, if states propose to add additional provider preventable conditions and in additional settings.

NAPH and its members fully support activities and initiatives that improve the quality of Medicaid programs through identifying and addressing patient safety issues. That said, CMS should explicitly require more partnership in developing and approving such policies, just as the agency has implemented for the Medicare HAC program. Without such review, the proposed regulatory standard that a condition “could have reasonably been prevented through the application of evidence based guidelines” could be broadly interpreted to include conditions around which there is not significant consensus. CMS partnered extensively with the external community when developing Medicare HACs, and there should be similar treatment when CMS receives SPAs with Medicaid HCAC proposals. As part of meeting the criteria for a PPC, states should be required to make demonstrations consistent with the principles outlined above.

Specifically related to the principle that any HCAC should be reasonably detectable, CMS notes in the preamble that the OIG has questioned the use of current present on admission (“POA”) indicators, stating that tools like the Institute for Healthcare Improvement’s Global Trigger Tool are considered much more effective in detection than the POA system.⁸ This is a critical point, because providers will be unfairly penalized for conditions that were in fact present but were not detectable. CMS should not approve a HCAC proposal if it cannot reasonably be identified on admission using the POA system, which CMS proposes that states will use in identifying HCACs.⁹

While NAPH appreciates that state flexibility is a hallmark of the Medicaid program, we also question whether patient safety issues and HCAC nonpayment policies to address them should vary significantly across different states or “health marketplace[s].”¹⁰ Certainly the Medicaid program is different than the Medicare program, and as such, different or additional HCACs may be appropriate and states should be active partners in identifying them. However, CMS should have a role in determining a specific and consistent definition¹¹ of the condition and whether there is a consistent evidence base for determining that a condition is reasonably preventable and identifiable. If there is, CMS should require consistent implementation by states seeking to address such a condition. This could result in CMS developing, for example, a list of

⁸ *Id.* at 9290.

⁹ *Id.*

¹⁰ *Id.* at 9288.

¹¹ Variability in state definitions could have a significant impact on a provider’s ability to detect a condition, resulting in inconsistent implementation of HAC policies and inconsistent impacts on quality. A standardized and specific definition would be particularly important for the following current Medicare HACs: intracranial injuries, crushing injuries, manifestations of poor glycemic control, catheter-associated urinary tract infection (UTI), vascular catheter-associated infection, coronary artery bypass graft (CABG)-mediastinitis (particularly mediastinitis), bariatric surgery (this is a very small surgical patient population so there should be a high degree of standardization in definitions of infections as variances in definitions could have a significant negative impact), deep vein thrombosis (DVT)/pulmonary embolism (PE) (as there are multiple methods for diagnosing, including pure clinical observation and high tech methods).

approved Medicaid HCACs with specific definitions that have been through the rigorous review process described above and from which other states could choose.

3. CMS should review the appropriateness of new Medicare HACs before prohibiting payment for such conditions under Medicaid.

Section 2702 states that “the Secretary may exclude certain conditions identified under title XVIII of the Social Security Act for non-payment under title XIX of such Act when the Secretary finds the inclusion of such conditions to be inapplicable to beneficiaries under title XIX.”¹² The proposed regulation at 42 C.F.R. § 447.26, however, does not provide for this exclusion. It defines HCACs to include “a condition identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) for of the Act for purposes of the Medicare program,” and states that “FFP will not be available for any State expenditure for provider-preventable conditions” defined to include HCACs.¹³ CMS should explicitly be required to review the appropriateness of a new HAC for the Medicaid program before it prohibits FFP for that HAC, and the final regulations should qualify the definition of HCACs to allow for the possibility that CMS may exclude certain Medicare HACs.

NAPH proposes the following changes to the proposed regulations to address the issues identified in comments #1, #2, and #3:

- CMS should amend the definition of “Health care-acquired condition” in Section 447.26(b) to read as follows: “Health care-acquired condition means:
 - (i) a condition identified as a HAC by the Secretary under section 1886(d)(4)(D)(iv) of the Act for purposes of the Medicare program, *excluding any conditions that the Secretary identifies to be inapplicable to Medicaid beneficiaries*, and
 - (ii) other HACs identified in the State plan *that CMS identifies as appropriate for application to the Medicaid program*.
 - (A) *In order to be appropriate for the Medicaid program, CMS must determine, through a process similar to that of the review process for Medicare HACs, that other HACs meet the requirements described in section 1886(d)(4)(D)(ii) and (iv) of the Act.*
 - (B) *CMS must also determine that the state has demonstrated the proposed HACs are consistent with the following principles:*
 - (1) *Address the patient safety issues of most concern for the Medicaid program*
 - (2) *Are limited to conditions for which there is clear scientific evidence and practical experience demonstrating that the HCAC is reasonably preventable, taking into account that safety net providers often treat vulnerable patients with multiple comorbidities*

¹² ACA § 2702(c).

¹³ Proposed 42 C.F.R § 447.26(b)-(c).

(3) Are limited to conditions for which there is clear scientific evidence and practical experience demonstrating that the HCAC is reasonably detectable, taking into account that safety net providers often treat vulnerable patients with multiple comorbidities

(4) Include only conditions researched and vetted by experts, including the provider community

(5) Will not reduce access by discouraging hospitals from taking the highest risk patients or penalize the safety net hospitals that, by their missions, are dedicated to treating those patients

(6) Are driven by patient safety and not a quest for cost savings”

- CMS should amend the definition of “other provider-preventable condition” in Section 447.26(b) to read as follows: “Other provider-preventable condition means a condition occurring in any health care setting *that CMS identifies as appropriate for application to the Medicaid program.*

(i) In order to be appropriate for the Medicaid program, CMS must determine, through a process similar to that of the review process for Medicare HACs, that the proposed other provider-preventable conditions meet the following criteria:

(A) Could have reasonably been prevented through the application of evidence based guidelines, as determined by CMS, in conjunction with agency partners and other experts as appropriate

(B) Has a negative consequence for the beneficiary

(C) Is identified in the State plan

(D) Is auditable

(E) Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part surgical or other invasive procedure performed on the wrong patient

(ii) CMS must also determine that the state has demonstrated the proposed PPCs are consistent with the principles outlined for other HACs identified by the state in the definition of Health care-acquired conditions.”

4. CMS should provide additional clarification on the definition of “other provider-preventable conditions.”

According to the Proposed Rule, a PPC means “a condition occurring in any health care setting that meets the following criteria:

(i) Could have reasonably been prevented through the application of evidence based guidelines

(ii) Has a negative consequence for the beneficiary

(iii) Is identified in the State plan

- (iv) Is auditable
- (v) Includes, at a minimum, wrong surgical or other invasive procedure performed on a patient; surgical or other invasive procedure performed on the wrong body part; surgical or other invasive procedure performed on the wrong patient”¹⁴

NAPH suggests above that CMS should have a role—whether on its own or in conjunction with AHRQ, CDC, or other appropriate experts—in determining what is the definitive evidence-based guideline for a particular condition. If CMS chooses not to assume such a role, we request that CMS provide additional guidance in the Final Rule, particularly if states may present differing evidence-based guidelines.

NAPH also requests that CMS provide further guidance in both the preamble and the regulatory language of § 447.26(b) on what it means to have a “negative consequence for the beneficiary” and should review compliance with this criteria based on a standardized definition of harm to provide some consistency across states and to assist providers as they design programs to reduce preventable conditions. Such standard harm definitions currently exist—for example, the Institute for Healthcare Improvement’s Global Trigger Tool.¹⁵

5. CMS should provide further guidance around adjustment of payments where states do not pay on a DRG basis.

As CMS acknowledges in the preamble, not all states pay on a DRG basis, but instead use per diem rates or other methodologies—for example, nine states pay hospitals a per diem amount and five states pay for inpatient services based on each individual hospital’s reported costs.¹⁶ CMS proposes that the state can reduce provider payments where it can “reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to the provider-preventable conditions.”¹⁷ In the context of per diem rates, CMS advises that “the state may need to isolate the increased cost of the services (possibly through a utilization review) and reduce the per diem reimbursement accordingly.”¹⁸

Where CMS identifies a HAC as a secondary diagnosis, Medicare will still pay the DRG amount but does not apply the severity adjustment if it is based on the HAC. However, providers often still receive higher Medicare payments for complicated patients because they have other comorbidities that justify the increase. (We refer you to the comments of the American Hospital Association for a more detailed discussion of this issue.) CMS should acknowledge this point in the preamble to the Final Rule and ensure that this is also the case where Medicaid pays using DRG reimbursement. Where the state pays flat per diem rates, CMS

¹⁴ Proposed 42 C.F.R. § 447.62(b).

¹⁵ See Griffin FA, Resar RK. IHI Global Trigger Tool for Measuring Adverse Events (Second Edition). IHI Innovation Series white paper. Cambridge, MA: Institute for Healthcare Improvement; 2009.

¹⁶ Medicaid and CHIP Payment and Access Commission. *Report to the Congress on Medicaid and CHIP*. March 2011.

¹⁷ Proposed 42 C.F.R. § 447.62(c)(2)(ii).

¹⁸ 76 Fed. Reg. at 9289.

should require that there be similar consideration of whether other comorbidities justify the full rate. CMS should also clarify that if the state cannot reasonably isolate a portion of the per diem or other rate, the state may not simply deny whole days or entire patient stays.

The purpose of this provision is to improve quality and safety, not to simply reduce state costs. As CMS states in the preamble, “we do not believe that beneficiaries would be best served by this policy if the focus was shifted from quality to system cost containment.”¹⁹ CMS should ensure that this policy provides the intended incentive to improve patient safety, not to instead discourage providers from treating complex patients.

In addition to the discussion and clarifications that we request CMS include in the preamble to the Final Rule, NAPH proposes the following changes to proposed § 447.26(c) to address this issue:

“(2) Reductions in provider payment may be limited to the extent that the following apply:

- (i) The identified provider preventable conditions would otherwise result in an increase in payment.
- (ii) *As approved by CMS*, the State can reasonably isolate for nonpayment the portion of the payment directly related to treatment for, and related to, the provider preventable conditions. *The State is not permitted to deny full payment where the State is unable to reasonably isolate the portion of the payment attributable to the provider preventable condition.*
- (iii) *States should not reduce provider payments to the extent that other conditions are present that would justify the full payment amount.”*

Finally, CMS states in the preamble that “nothing in this rule prevents a [s]tate from reinvesting any savings it may achieve from nonpayment of PPCs into rate improvements aimed at achieving improved access to care, as appropriate.”²⁰ NAPH strongly supports the use of such savings toward rate improvements to support Medicaid providers in serving their patients and asks CMS to consider actions to encourage such investment, given that in current state fiscal situations, states are otherwise unlikely to reinvest savings into the program.

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¹⁹ *Id.* at 9290.

²⁰ *Id.*

NAPH appreciates CMS' consideration of these comments. If you have any questions, please contact Xiaoyi Huang at (202) 585-0100.

Sincerely,

A handwritten signature in black ink, appearing to read "Bruce Siegel", with a stylized flourish at the end.

Bruce Siegel, MD, MPH
Chief Executive Officer