



August 30, 2010

Donald Berwick, M.D.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1504-P
P.O. Box 8013
Baltimore, MD 21244-1850

RE: CMS-1504-P, Medicare Program; Proposed Changes to the Hospital Outpatient Prospective Payment System and CY 2011 Payment Rates; Proposed Changes to the ASC Payment System and CY 2011 Payment Rates; Proposed Changes to Payments to Hospitals for Certain Inpatient Hospital Services and for GME Costs; and Proposed Changes to Physician Self-Referral Rules; Proposed Rule (Vol. 75, No. 148), August 3, 2010.

Dear Dr. Berwick:

On behalf of our 26 acute care member hospitals New Hampshire Hospital Association (NHHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) hospital outpatient prospective payment system (OPPS), ambulatory surgical center (ASC), graduate medical education costs and physician self-referral proposed rule for 2011.

The NHHA has serious concerns about CMS' proposal for supervision of outpatient therapeutic services, the requirements for outpatient quality data reporting, the payment rates for separately payable drugs, the continuing failure of CMS to require ASC quality and cost reporting and the lack of information needed to comment on the ASC productivity adjustment factor. The NHHA supports the detailed comments made by the American Hospital Association and provides the following recommendations:

PROPOSED POLICIES FOR SUPERVISION OF OUTPATIENT THERAPEUTIC SERVICES

CMS' proposed change to its direct supervision policy marks a very small step in the right direction, primarily because the agency is finally acknowledging that not all services covered by Medicare in hospital outpatient departments require direct supervision. **However, the agency's proposal does not go nearly far enough to assure continued access to the full range of outpatient therapeutic services in hospitals, particularly for small and rural facilities, such CAHs.** There are many other procedures that can be, and are, safely furnished in hospital outpatient departments under the general supervision of a physician.

The NHHA recommends a more comprehensive and clinically appropriate approach for providing supervision for therapeutic services that we believe will provide for high quality and safe patient care without hampering access through unnecessarily onerous requirements for less risky and complex services.

For calendar year (CY) 2011, CMS proposes "modest" changes to its supervision policy for outpatient therapeutic services that would apply to all hospitals, including critical access hospitals (CAHs). Specifically, CMS identifies a small set "nonsurgical extended duration therapeutic services" for which a new hybrid level of supervision is proposed. For these services, CMS proposes to require direct supervision for the initiation of the service followed by general supervision for the remainder of the service.

While our response addresses some of the issues for which CMS is seeking feedback, our comments below also propose a more comprehensive and clinically appropriate approach for providing supervision for therapeutic services that we believe will preserve high quality and safe patient care without hampering access through unnecessarily onerous supervision requirements. Because a more comprehensive supervision policy will take time to establish, and, in the meantime, CAHs and other small and rural prospective payment system (PPS) hospitals are largely unable to comply with the requirements of the new supervision regulations, we recommend that CMS extend through 2011 the enforcement moratorium currently in place for CAHs and also apply it to other small and rural PPS hospitals located in communities with shortages of health professionals. In addition, the AHA continues to disagree with CMS' repeated assertion that in the 2009 final rule the agency was merely restating and clarifying its existing direct supervision policy dating back to 2000, and we object to the application of this policy to outpatient therapeutic services furnished since 2001.

Proposed Supervision Requirements for "Nonsurgical Extended Duration Therapeutic Services"

In the rule, CMS defines a set of 16 "nonsurgical extended duration therapeutic services" as those services with a significant monitoring component that can extend for a sizable period of time, are not surgical and typically have a low risk of complication. CMS proposes that these services would be subject to direct supervision only for the initiation of the service followed by general supervision for the remainder of the service. CMS

proposes to adopt the definition of “general supervision” used for diagnostic services, meaning that the procedure is furnished under a physician’s overall direction and control, but the physician’s presence is not required when the procedure is performed.

CMS describes this policy as the agency’s response to the significant correspondence and concerns voiced by CAHs and rural hospitals, and a way to offer flexibility within the supervision requirements while continuing to ensure that Medicare-purchased outpatient therapeutic services are delivered with a “basic level of quality and safety” and consistent with *Social Security Act’s* requirements that these are “incident to” physician services. According to CMS, the services that CAHs identified as particularly challenging from the direct supervision perspective included observation and chemotherapy, which have extended duration and a significant monitoring component that could extend after business hours. By proposing to allow a reduced level of supervision to apply for a portion of some of these services, CMS believes that it is providing flexibility to CAHs and to other hospitals.

While the NHHA appreciates CMS’ efforts to respond to CAHs’ concerns and its attempt to provide additional flexibility, we do not believe that the policy as proposed will provide substantive regulatory relief for CAHs or other hospitals that are located in communities with health professional shortages.

There are several problems with CMS’ proposed hybrid supervision policy. First, the level of supervision required for the “initiation” of these 16 services is direct supervision. For practical purposes, this means that a physician or NPP must be present in the hospital and immediately available at all times these services are available to the community both during and after normal business hours. In fact, all 16 of the services included in CMS’ list of “nonsurgical extended duration therapeutic services” are typically provided by hospitals and CAHs 24 hours a day, 7 days a week (24/7). Thus, a physician or NPP must be present in the CAH at all times in case a patient presents requiring any of these services. While in some CAHs and rural hospitals an emergency physician could provide this 24/7 level of supervisory presence, the ambiguity in CMS’ policy regarding whether an emergency physician is truly “immediately available” and also “clinically appropriate” to supervise a wide range of outpatient services, makes this a tenuous solution at best. **If these 16 services truly have a low risk of complication after initial assessment, and if, as is currently the case with CAHs, such an assessment can be made by trained qualified ancillary staff who are directly communicating with an on-call physician or NPP by telephone, radio or other means, the NHHA contends that these services, in their entirety, should be permitted to be provided under the *general supervision* of a physician or NPP.**

We also are concerned that CMS’ proposed policy could subject supervising physicians and NPPs to untenable levels of enforcement scrutiny regarding the clinical appropriateness of their decisions to move patients from direct to general supervision upon completion of the “initiation” phase of a service on the list. While we agree that the determination that a patient is sufficiently stable to transfer from direct to general supervision and the timing of that decision should not be defined by CMS policy, but left to a physician’s or NPP’s clinical judgment, the policy itself is ripe with opportunities for CMS’ contractors, such as recovery audit contractors, to second-guess the clinical

judgment of the supervising physician or NPP. Moreover, requirement to document this point of transfer from direct to general supervision would be burdensome and only add to the mountains of paperwork already required of physicians, without contributing to patient safety or quality of care.

Also, and most importantly, the list of services subject to a reduced level of supervision is too limited. There are numerous other outpatient therapeutic services that are covered by Medicare, including additional extended duration services, certain short duration services, certain minor surgical procedures and the recovery portion of certain surgical services, which could be provided safely under general supervision.

The NHHA also disagrees with CMS' decision to exclude all surgical services, including the recovery period of certain surgeries, from consideration for a reduced level of supervision. In the proposed rule CMS does not explain its rationale for excluding all surgical services from consideration. We believe that there may be many low-risk, minor surgical procedures that could be performed safely under general supervision in a hospital outpatient department. Further, CMS does not adequately explain why it is excluding the surgical recovery period from consideration. The agency only states, "although monitoring of any patient in recovery is a key component of surgery, it is not the focus or a substantial component of the service and because we believe the surgeon should personally evaluate the patient's medical status during the recovery period." The AHA agrees that a surgeon and, as appropriate, an anesthesiologist or certified registered nurse anesthetist, should evaluate the patient's medical status for some portion of the surgical recovery period. However, we believe that for many types of surgeries, there is a point during the recovery period, perhaps after the patient has been cleared by the anesthesiologist, when it would be safe for the level of supervision to transition from direct to general.

A New Approach is Needed for the Supervision of Outpatient Therapeutic Services

Despite the marginal changes CMS made in the 2010 supervision policy and those CMS is proposing for 2011, hospitals and CAHs remain concerned about the implications of the agency's burdensome, unnecessary and short-sighted policies. Continuing to fine-tune this ultimately unworkable and unwarranted policy through frequent sub-regulatory reinterpretation and annually through minor regulatory changes is not appropriate.

Hospitals, CAHs and the patients they serve deserve a policy that is comprehensive, based on clinical input and data, stable and that will ensure ongoing access to high-quality patient care. In the paragraphs below we describe why the current CMS policy is not working and our vision for a more comprehensive policy that should be adopted.

CMS' supervision policy is unwarranted. CMS offers no real clinical or quality basis for its new and burdensome supervision requirements. In fact, the agency has presented no evidence that patient safety or quality of care has been compromised in past years due to inadequate or ineffective supervision.

Hospital outpatient therapeutic services have always been provided with the highest quality of care principles in mind. These services are ordered by the patient's treating physician, who is responsible for assessing the patient's progress and, when necessary, changing the treatment regimen. Many services are furnished in the hospital outpatient

department by licensed, skilled professionals under the overall direction of a physician or a NPP.

For many low-risk and low-complexity services, a physician does not need to be physically present in order for hospital staff to provide safe and high-quality outpatient care. This is because non-physician hospital staff are competent, licensed health care professionals who provide services that fall within their scope of practice in accordance with state law. Further, the provision of care is governed by clinical protocols, policies and procedures that are approved by the hospital's medical staff. Non-physician staff can contact a physician by phone, radio or other means if needed for routine consultation.

Should an unforeseen situation arise, medical staff physicians can be promptly summoned. The Joint Commission's National Patient Safety Goals state that rapid response teams are to be in place to provide assistance. If a patient emergency arises, the rapid response team, including a physician, is available to provide care.

Due to continuing shortages of physicians and NPPs, many hospitals and CAHs are finding it difficult, if not impossible, to meet CMS' supervision requirements. There are inadequate numbers of physicians and other NPPs available to provide direct supervision, particularly in rural areas. Therefore, the marginal additional flexibility CMS provided in the 2010 OPSS final rule to permit certain NPPs to provide direct supervision for outpatient therapeutic services does not go far enough. Moreover, CMS' added flexibility would not apply to certain outpatient services, such as cardiac and pulmonary rehabilitation and certain diagnostic services, which CMS states may only be supervised by a physician. A shortage of physicians and NPPs in rural and other communities dilutes the utility of CMS' more flexible policy. Additionally, as noted earlier, CMS' proposed policy for 2011 also fails to adequately address the concerns that hospitals and CAHs have raised. The proposal would only apply to a small set of services, still require direct supervision by a physician or NPP for the initiation portion of these services, and subject the supervising professional to additional enforcement scrutiny.

CMS' requirements are overly restrictive. CMS' supervision requirements severely restrict the ability of hospitals and CAHs to effectively use their existing staff to make supervisory assignments and leave them with limited options to comply.

CMS needs to make a fundamental change in its supervision policy. A more comprehensive and clinically-based approach is needed for assigning levels of physician supervision to outpatient therapeutic services. Medicare covers and pays for outpatient therapeutic hospital services as services furnished "incident to" a physician's service, as described in *Social Security Act* §1861(s)(2)(B). The law does not mandate a specific level of physician supervision for "incident to" services. CMS possess the regulatory discretion to determine the appropriate level of supervision for these services.

The NHHA recommends that CMS adopt a default standard of “general supervision” for outpatient therapeutic services. However, because we recognize there are high-risk and complex services furnished in hospital outpatient departments that would benefit from a higher level of supervision, an exceptions process should be established to identify specific procedures that should be subject to direct supervision. Such an exceptions process should involve recommendations from a clinical expert panel composed of physicians and NPPs who practice in hospital outpatient departments in urban and rural communities, including CAHs, and whose specialties reflect the range of services covered by Medicare in hospital outpatient departments. Further, to ensure full and appropriate consideration for the services recommended for designation as requiring direct supervision, the recommendations from the clinical expert panel should be subject to notice and comment through a public rulemaking process.

A special rule should be established for CAHs in recognition of their unique personnel CoPs. In order to allow CAHs to continue to furnish a wide range of services to their communities, including those outpatient therapeutic services determined through the exceptions process to require direct supervision, CAHs should be considered to be in compliance with the direct supervision requirements for a service if they comply with the CoP standard for personnel required under 42 CFR 485.618. That is, when a service requiring direct supervision is furnished in a CAH, the on-call supervising physician or NPP arrives in the CAH within 30 minutes of being called.

The NHHA recommends that CMS revise the definition of “direct supervision” for outpatient therapeutic services furnished in hospitals and in on-campus and off-campus provider-based departments to allow physicians and NPPs to be “immediately available” in ways other than just appearing in person. With this Administration’s focus on advancing the applications of technology in health care, including telemedicine and robotic technologies for health care delivery, we recommend that direct supervision should explicitly include, as appropriate, response via radio or telephone, or through other technologies approved for use in Medicare, such as telemedicine.

The NHHA recommends that CMS revise the definition of “direct supervision” for outpatient therapeutic services furnished in an off-campus provider-based department to allow the supervising professional to be present in the department or “in close proximity” to the department. Many hospitals place their off-campus provider-based departments in medical office buildings that also house the private physician practices from which supervising physicians are drawn. Under the 2010 direct supervision policy, a physician located in a private office in a suite adjacent to the hospital’s off-campus provider-based department would not be in compliance with the requirements for direct supervision, despite being “immediately available” because he is not physically present in the hospital outpatient department when the outpatient therapeutic services are furnished.

We recognize that a more reasonable and comprehensive supervision policy, as described above, will take at least a year to establish and implement, and, in the meantime, many CAHs and other small and rural PPS hospitals will remain unable to comply with the requirements of the direct supervision regulations. **Therefore, the NHHA also recommends that CMS extend through CY 2011 the enforcement moratorium that is currently in place for CAHs and also apply the moratorium to other small and rural PPS hospitals located in communities that are experiencing health professional shortages.** As CMS notes in the proposed rule, its decision not to enforce the rules for supervision of hospital outpatient therapeutic procedures furnished in CAHs in CY 2010 was in response to rising concerns among the rural community about the rules and the inability of hospitals to meet the direct supervision requirements. As we describe above, CMS' proposed "hybrid" supervision policy for 16 services also will not provide much assistance to CAHs or other small hospitals in medically underserved areas. While the AHA's preferred approach would enable CAHs and other hospitals to continue to provide access to covered outpatient services in such medically underserved areas, given the lead time for putting the new system into place, additional relief is necessary for CAHs and other small and rural PPS hospitals.

PAYMENT FOR OUTPATIENT DRUGS

We recommend that CMS abandon its current methodology for calculating the payment rate for separately covered outpatient drugs due to its instability. Instead, the agency should pay for the acquisition cost of separately covered outpatient drugs at the rate at which they are paid in physician offices, currently ASP plus 6 percent. The law permits CMS to use this payment rate as an alternative.

OPPS: HOSPITAL VISITS

Since April 2000, hospitals have been using the American Medical Association's (AMA) CPT evaluation and management (E/M) codes to report facility resources for clinic and emergency department (ED) visits. Recognizing that the E/M descriptors, which were designed to reflect the activities of physicians, did not adequately describe the range and mix of services provided by hospitals, CMS instructed hospitals to develop internal hospital guidelines to determine the level of clinic or ED services. In 2003, the AHA and the American Health Information Management Association (AHIMA) recommended that CMS implement national hospital E/M visit guidelines based on the work of an independent expert panel comprised of representatives with coding, health information management, documentation, billing, nursing, finance, auditing and medical experience.

For 2011, as it has for every year since implementing OPSS, CMS proposes that until national guidelines are established, hospitals should continue to report visits according to their own internal hospital guidelines to determine the different levels of clinic and ED visits. In the proposed rule, CMS notes its continued expectation that hospitals' internal guidelines would comport with the principles listed in the 2008 OPSS/ASC final rule. Hospitals with more specific questions related to the creation of internal guidelines are to contact their local fiscal intermediaries or Medicare Administrative Contractors.

The NHHA is deeply concerned that CMS does not appear interested in developing or approving national guidelines for the reporting of hospital ED or clinic visits.

Since the implementation of the OPSS, the AHA has advocated for national guidelines and unique codes to represent facility resources, rather than physician resources, used in the delivery of clinic and ED visits. CMS has poor data to calculate crucial APC reimbursement since there is no standard definition or standard application of E/M codes. Hospitals are using different methodologies, such as those based on time, interventions, patient complexity or severity, and therefore each hospital's reported E/M levels reflect a different aspect of hospital resource utilization.

Commercial payers have begun to create their own guidelines and interpretations of hospital ED and clinic visit coding. One such inappropriate policy has just been adopted by Aetna. The lack of national guidelines places hospitals at risk of having different guidelines for different payers. Such lack of uniformity is complex and burdensome for hospitals, in addition to being an inappropriate source of conflict with commercial payers and auditors. **Given CMS' apparent lack of interest in adopting national guidelines, the AHA urges CMS to support a request to the AMA CPT Editorial Panel to create unique CPT codes for hospital reporting of ED and clinic visits based on internally developed guidelines.** These codes then could be widely reported by hospitals to all payers.

GRADUATE MEDICAL EDUCATION (GME)

CMS should not eliminate residency slots from hospitals unless they are training below their residency caps in all three of the most recent cost reporting years.

WHOLE HOSPITAL AND RURAL PROVIDER EXCEPTIONS TO THE PHYSICIAN SELF-REFERRAL PROHIBITION

The NHHA recommends that CMS continue to adhere closely to the statutory language of Sec. 6001 of the *Patient Protection and Affordable Care Act* that addresses the whole hospital and rural provider exceptions to the physician self-referral prohibition and related congressional intent.

OUTPATIENT PPS: QUALITY DATA

The Tax Relief and Health Care Act of 2006 mandated that CMS establish a program under which hospitals must report data on the quality of hospital outpatient care to receive their full annual update to the outpatient PPS payment rate. Beginning in 2009, hospitals that fail to report data incur a reduction in their annual payment update factor of 2.0 percentage points.

A Vision for Reporting Quality Measures

In the proposed rule, CMS outlined a three-year implementation plan for quality measures, thus, proposing a longer term vision for the outpatient quality reporting program. While we applaud CMS' intention of providing greater predictability about the

measures to be used in future years, we are concerned that this extended plan lacks a unified framework with clearly articulated goals of what CMS would like the outpatient reporting program to achieve. The proposal also fails to take into account important aspects of the ACA. The law clearly promotes greater integration of care across the delivery system. And, CMS' approach to measuring care for patients in the hospital inpatient and outpatient settings could begin to build an important framework for assessing care across the continuum. However, the proposal makes no mention of how the outpatient reporting program could work in concert with the inpatient program to portray a holistic picture of quality across the continuum of hospital care.

We urge CMS to make a stronger conceptual link between the two hospital reporting programs. We believe this is an important part of what Congress was seeking to achieve when it adopted provisions in the ACA to create a National Quality Strategy. The National Quality Strategy begins with the Secretary selecting national priorities that are intended to be the focal point for measurement, reporting and financial incentives. The use of a common set of priorities will help focus providers' quality improvement efforts on high-leverage, important areas and align the various national reporting programs among different health care providers and settings. A preliminary set of national priorities already exist in the work of the National Quality Forum's (NQF) National Priority Partners in which CMS and other federal agencies participate. The goal of the Partners' national priorities is to engage all stakeholders in a shared effort to make quality improvements in the most important areas of patient care. The Hospital Quality Alliance (HQA) agrees that the Partners' national goals should provide a foundation for its future work, and it would be beneficial for CMS to follow these national goals as well.

In the interests of transparency and equity, we continue to urge CMS to implement a quality reporting system for ASCs as soon as possible. Also, in order to allow for future validation of the appropriateness of ASC payment weights and rates, we continue to recommend that CMS require ASCs to begin to routinely report cost data.

Thank you again for the opportunity to comment. If you have any questions, please contact me or Paula Minnehan, VP, Finance and Rural Hospitals, (603) 415-4254 or pminnehan@nhha.org

Sincerely,



Steve Ahnen,
President