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August 28, 2008

Kerry N. Weems
Acting Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

RE: CMS-1403-P, Medicare Program; Proposed Revisions to Payment Policies Under the Physician Fee Schedule and Other Part B for CY 2009; Proposed Rule (Vol. 73, No. 130), July 7, 2008.

Dear Mr. Weems:

On behalf of our more than 5,000 member hospitals, health systems and other health care organizations, and our 38,000 individual members, the American Hospital Association (AHA) appreciates the opportunity to comment on the Centers for Medicare & Medicaid Services' (CMS) physician fee schedule proposed rule for calendar year (CY) 2009. Our remarks pertain specifically to the provisions for independent diagnostic testing facilities (IDTFs), especially the mobile entity billing requirements.

Independent Diagnostic Testing Facilities

Under the proposed rule, entities that furnish mobile diagnostic services would be required to enroll in Medicare as IDTFs, comply with IDTF performance standards and directly bill Medicare for the mobile diagnostic services that they furnish, regardless of where the services are performed.

We are concerned that CMS does not recognize this proposal's broader implications for hospitals that use mobile diagnostic testing facilities to provide imaging and other services to their patients. In these commonplace arrangements, the mobile facilities provide services to hospital patients through a contract, lease, shared services agreement or other leasing arrangement, and the services are billed by the hospital using the "under arrangements" provision.



The AHA urges CMS to clarify that its proposal to require mobile diagnostic testing entities to bill directly for services they furnish would not apply when such services are provided “under arrangements” to hospital inpatients and outpatients. CMS’ proposed billing requirements, if extended to hospital-mobile diagnostic testing leasing arrangements, would disrupt these long-standing arrangements and, more importantly, conflict with the prohibition against unbundling of hospital services.

Section 1862(a)(14) of the *Social Security Act* prohibits payment for non-physician services furnished to hospital patients (both inpatients and outpatients) unless the services are furnished by the hospital, either directly or under arrangement. In the April 7, 2000 *Federal Register* CMS states, “All diagnostic tests that are furnished by a hospital, directly or under arrangements, to a registered hospital outpatient during an encounter at a hospital are subject to the bundling requirements.” CMS also states that a freestanding entity providing diagnostic tests may bill only for services furnished to beneficiaries who do not meet the definition of a hospital outpatient at the time the services are furnished. Similarly, under the Medicare inpatient prospective payment system, payments for diagnostic services, regardless of whether the services are provided directly by the hospital or “under arrangements,” are bundled into the diagnostic related group (DRG) payment and separate payment for these services to another entity would be prohibited. In fact, the Office of Inspector General may impose a penalty of up to \$2,000 for each bill or request for items and services furnished to hospital patients in violation of the bundling requirements.

The AHA also recommends that mobile diagnostic testing facilities that provide these services to hospitals be excluded from the proposed IDTF performance standards. We recognize and support CMS’ initiatives to improve the quality of all health care services, including diagnostic testing services, in the hospital setting. However, there are numerous existing requirements to ensure that mobile diagnostic testing services are integrated sufficiently within the hospital and subject to hospital oversight and other Medicare requirements:

- The hospital Medicare conditions of participation for contracted services, at 42 CFR 482.12(e), require the hospital to retain responsibility and implement quality controls for all services furnished in the hospital, whether provided directly or indirectly by the hospital.
- The Medicare manual provision, *Under Arrangements* (CMS Pub. 110-01 Chapter 10.3), reinforces quality oversight, requiring that when hospitals procure services under arrangements, they exercise professional responsibility over the arranged-for services. This section states, “The provider’s professional supervision over arranged-for services requires application of many of the same quality controls as are applied to services furnished by salaried employees.” This includes a requirement to have the same admission policies in place that the hospital has for all patients and to maintain clinical records on the patient that include diagnoses, medical history, physician’s orders and progress notes.
- In the case of mobile-leasing arrangements, the mobile company provides the service as a component of the hospital’s overall radiology/imaging department. Medical records are maintained by the hospital provider, and patients receiving radiology services are

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registered as hospital inpatients or outpatients with hospital quality assurance provisions applicable to the provision of services furnished by such mobile companies.

- Hospitals that are accredited by The Joint Commission – representing the majority of hospitals in the United States – are accountable for the quality of care provided to their patients by entities with which they contract to provide services. That is, contracted services are held to the same standards as services that are provided directly by the hospital.

If you have any questions about these comments, please feel free to contact me or Roslyne Schulman, senior associate director for policy, at (202) 626-2273 or rschulman@aha.org.

Sincerely,

Rick Pollack

Executive Vice President