
*Avera Health (IA, MN, NE, ND, SD)*

*Carolinas HealthCare System (NC, SC)*

*Community Hospital Anderson (IN)*

*Erlanger Medical Center (TN)*

*Fletcher Allen Health Care (VT)*

*Forrest General Hospital (MS)*

*Franciscan Missionaries of*

*Our Lady Health System (LA)*

*Harris Health System (TX)*

*Hartford Hospital (CT)*

*Health First Inc. (FL)*

*Kaiser Permanente (CA)*

*Mercy Health System (AR, KS, LA, MS,MO, OK, TX)*

*Ohio Valley Health Services and Education Corporation (OH, WV)*

*Raritan Bay Medical Center (NJ)*

*Robert Wood Johnson University Hospital (NJ)*

*University Health System (TX)*

*University of Pittsburgh Medical Center (PA)*

*Virtua (NJ)*

Ms. Marilyn Tavenner
Administrator
Centers for Medicare & Medicaid Services
Hubert H. Humphrey Building
200 Independence Avenue, S.W., Room 445-G
Washington, DC 20201

September 7, 2013

Reference: **[CMS–1600–P] Medicare Program; Revisions to Payment Policies under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014**

Dear Ms. Tavenner,

The following comments are submitted by the Provider Roundtable (PRT), a group composed of providers who gathered to generate comments on the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B Proposed Rule, as published in the *Federal Register* on July 19, 2013.

The Provider Roundtable (PRT) includes representatives from 18 different health systems from around the country. PRT members are employees of hospitals. As such, we have financial interest in fair and proper payment for hospital services, but do not have any specific financial relationship with vendors.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual MPFS policymaking and recalibration process. We appreciate the opportunity to provide our comments to CMS. A full list of the current PRT members is provided in **Attachment A.**

Please feel free to contact me at 225-765-8847 or via email at: *Jen21306@ololrmc.com*.

Sincerely,

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**Collecting Data on Services Furnished in Off-Campus Hospital Provider-Based Departments**

The PRT has offered the following comments in response to CMS-1601-P (the Hospital OPPS Proposed Rule for Calendar Year 2014):

> The PRT understands that CMS seeks feedback and proposals on the best way to collect information on the frequency, type, and payment of services provided in off-campus provider-based hospital departments. We believe this interest stems, in part, from the agency's belief that hospitals and health systems acquire physician practices in order to subsequently convert them to provider-based clinics.
>
> We disagree with this belief, since our experience indicates that, in many cases, hospital-owned physician practices remain freestanding physician practices. In other cases, hospitals and health systems make individual determinations for each practice and location in order to deliver optimal patient care —including being able to offer new services as a benefit to enable patients' better access to high-quality health care. If a hospital chooses to make the investment and develop provider-based clinics, it often represents new services offered within the community; this benefits patients and enables access to integrated health care services that are only available via hospital-based care.
>
> With respect to CMS' interest in gathering data on services delivered through provider-based locations, and its proposals on a process for doing so, the PRT first seeks clarification about how CMS intends to use the collected data. We want to understand if the intended use will justify and offset the *significant* administrative burden providers would face from any new reporting requirements.
>
> Before CMS considers any sort of claim-level or cost reporting data collection, the PRT recommends that the agency mandate the completion of the provider-based attestation for *all* provider-based departments. This attestation is currently voluntary. CMS has already outlined the requirements hospitals must meet for provider-based departments; these requirements contribute to higher costs associated with the greater integration of these clinics with the hospitals that own and operate them.
>
> Costs in the hospital environment, including costs in provider-based departments, are much higher than costs in freestanding physician offices. As previously noted, many of the costs are regulated by CMS to ensure the provider-based clinics are integrated with the hospital that owns and operates them. These costs reflect additional services available to the patients (i.e., emergent care and higher resource utilization, including 24/7 staffing and higher overhead costs that are associated with accreditation). We believe that cost reporting of such clinics under current instructions represents an accurate method to identify costs. We further encourage CMS to clarify instructions for overhead cost allocation to such provider-based departments once the agency mandates the attestation process.
>
> The PRT notes, however, that many of its members have experienced significant delays

in their MACs processing the attestations. For this reason, we request CMS to allow providers that believe they meet the attestation criteria for provider-based clinics to bill outpatient hospital claims, and receive APC payments for those locations, after filing the attestation but before receiving formal MAC approval. (This resembles the current process.)

The PRT is also concerned about whether CMS expects modifiers to be used solely for services rendered in off-campus provider-based departments. We are not clear how CMS will track whether there were different services provided in two *separate* provider-based off campus locations on the same day for the same beneficiary. Does CMS want the modifiers to be so specific that it will track each address (or location) where services are rendered, or just whether some services were rendered off-campus (with unmodified services representing services that are delivered on-campus).

**In summary, the PRT recommends that, before requiring hospitals to incur the additional burden of reporting claim-level modifiers or making changes to our systems for revenue codes and/or changed cost reporting requirements, CMS should clarify and specify exactly *which services* would require a modifier.**

As it relates specifically to the Physician Fee Schedule (MPFS) Proposed Rule, the PRT supports CMS' suggestion of the creation of a new Place of Service code for off-campus departments of a provider under 42 CFR 413.65(g)(2) as part of item 24B of the CMS–1500 claim form, comparable to current place of service codes such as "22 Outpatient" and "23 Emergency Room-Hospital" when physician services are furnished in an off-campus provider-based department.

We believe this to be the least operationally burdensome claims-based approach for reporting the professional component of provider-based services on the professional claim form. We recognize that this approach does not make it possible for the facility fee to be reported on the institutional claim form. Therefore, we expect the CMS Physician and Outpatient Divisions to work closely together regarding the finalized data collection process. It is critical that these entities strive to minimize the operational impact on hospital providers whose professional and institutional claims will both be subject to this data collection process.

**Using OPPS and ASC Rates in Developing PE RVUs**

CMS establishes two different PE RVUs under the MPFS: facility and non-facility. In establishing facility PE RVUs, CMS generally excludes resources that would not be provided by physicians when the service is furnished in a facility setting. Because the facility PE RVUs are typically lower than non-facility PE RVUs, the total MPFS payment should typically be lower for services that physicians provide in a facility.

CMS cites various rationales and acknowledges that the facility generally incurs *higher* indirect costs to provide a service than would be required in the physicians' office setting. CMS states that, when services are furnished in the facility setting (e.g. HOPD or ASC), the total Medicare payment (MPFS + "Facility") typically exceeds the Medicare payment (MPFS only) when the same service is furnished in the physician office or other non-facility setting.

CMS has determined that, for some services, the total MPFS non-facility payment is *higher* than the MPFS + "Facility" payment. CMS believes that this is not due to actual appropriate differentials, but rather stems from inadequate (or inaccurate) reported data used to set PE RVUs. CMS relies on data submission for PE RVUs and has little means to validate the accuracy of the data that are submitted. The data are also not widely, or routinely, updated.

On the other hand, CMS believes that OPPS data are auditable, are frequently updated, and would serve as a valid proxy and point of comparison in establishing PE RVUs for services under the MPFS.

CMS proposes to compare the current year (proposed) MPFS payment rate for a service furnished in an office setting to the total Medicare payment to practitioners and facilities (the combined MPFS + "Facility" payment) for the same service when it is provided in a hospital outpatient setting. For services on the ASC list, CMS proposes to make the same comparison, with the exception that it would use the ASC rate as the point of comparison rather than the OPPS rate.

CMS proposes to limit the non-facility PE RVUs for individual codes so that the total non-facility MPFS payment amount would not exceed to the total combined amount Medicare would pay for the same code in the facility setting (combined MPFS + "Facility" payment). CMS also provides several reasonable exceptions to the policy. This process will affect approximately 200 codes in 2014, for which CMS believes the resource inputs are misvalued.

The PRT concurs with CMS' belief that this proposal provides a reliable means for Medicare to set upper payment limits for office-based procedures, using the assumption that facility costs in general are higher than office costs for providing identical services. The PRT agrees with CMS that, generally, hospital outpatient departments and ASCs incur greater costs for providing the same service than does a physician's office.

**We agree with, and support, CMS' proposal to limit the MPFS nonfacility PE RVU for individual codes based on the comparison to OPPS or ASC rates.**

**<u>Medicare Telehealth Services for the Physician Fee Schedule</u>**

In determining originating site eligibility, the PRT supports CMS' proposal to refine the definition of "rural" by categorizing rural HPSAs as those that are located in rural census tracts as determined by ORHP.

We also support CMS' proposal to maintain the facility eligibility list on an annual basis in concert with the other telehealth rulemaking processes. We believe that doing so will expand beneficiaries' access to care and provide greater stability for both providers and patients.

**The PRT agrees with the rationale and further supports the addition of CPT code 99495 (Transitional care management services with the following required elements to the list of approved telehealth services:**

- *Communication* (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge medical decision-making of at least moderate complexity during the service period face-to-face visit, within 14 calendar days of discharge; and
- *CPT code 99496* (Transitional care management services with the following required elements: Communication (direct contact, telephone, electronic) with the patient and/or caregiver within two business days of discharge medical decision-making of high complexity during the service period face-to-face visit, within seven calendar days of discharge).

**Application of Therapy Caps in CAHs**

It is unclear at this time if Congress will extend the current statutory regulation for beneficiary therapy caps until the end of CY 2013 and do not know whether it will extend this provision for CY 2014. The PRT does not, however, support the inclusion of CAHs in Therapy Caps.

**The PRT does not support the CMS proposal to place CAH under a different requirement from hospital outpatient departments.**

**Medicare Coverage of Items and Services in FDA Investigational Device Exemption Clinical Studies—Revision of Medicare Coverage and MAC Related Issues**

The PRT appreciates CMS' proposal to centralize the review process for Investigational Device Exemption (IDE) coverage determination. We can support this, as long as the new centralized process would result in timelier and simpler outcomes for the provider community. We are hopeful that CMS' proposed methodology would remove current inconsistencies and time lags among the various Medicare Administrative Contractors (MACs) regarding this approval process.

**The PRT specifically recommends that CMS implement a reasonable timeframe for a decision on the IDE request as part of its proposal; by "reasonable" we mean that decisions should be made within 30-45 days so that clinical trials can commence in a timely manner.**

We understand that CMS is proposing 13 standards that Category A and B device trials must meet in order for the costs of routine care items to be coverable. We also understand that investigational trials would automatically be covered if they meet these 13 requirements, where the study is a *"pivotal study*," and where *"the study has a superior study design."*

**While we support the 13 requirements in general, the PRT requests CMS to further explain what it means by *"pivotal study"* and *"superior study design,"* and how *"automatic coverage"* would be determined.**

Before we can fully support this proposal, we need clarification on the process involved in determining "automatic coverage" for a device trial, as well as how CMS will make the determination about *"pivotal study"* and *"superior study design."* We cannot support *any* changes that would make requirements more stringent than they are today.

**Along the same lines as centralizing the IDE coverage process, the PRT also requests CMS to consider centralizing the coverage determination of Category III codes.**

It has been the experience of PRT members that, like the IDE coverage determination, coverage determinations for the Category III codes also vary significantly among the MACs. Some contractors deny almost *all* Category III codes as not medically necessary. Other contractors suggest using the LCD reconsideration process to have Category III codes added as covered. Further, the reconsideration process is typically lengthy and does not address current patients who need the newest technological approaches.

Originally, the IDE coverage policy gave Medicare beneficiaries the opportunity to have earlier access to new medical devices; to further that goal, the PRT expects the proposed centralized process *not* to create any additional barriers to these devices.

**We request CMS to ensure that Medicare beneficiaries *also* have equal access to new technology procedures coded with the Category III CPT codes**. Medicare beneficiaries should not be excluded from receiving the most innovative approaches to medical care due to non-coverage issues. As the agency creates the centralized approach for IDE coverage, it seems logical for CMS to *also* fold-in national coverage consideration for Category III CPT codes.

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