
*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 (MS)*

*Franciscan Missionaries of Our Lady Health System (LA)*

*Harris Health System (TX)*

*Hartford Hospital (CT)*

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

*Raritan Bay Medical Center (NJ)*

*Robert Wood Johnson University Hospital (NJ)*

*University of Pittsburgh Medical Center (PA)*

September 2, 2014

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

Re: 42 CFR Parts 403, 405, 410, et al. Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule, Access to Identifiable Data for the Center for Medicare and Medicaid Innovation Models & Other Revisions to Part B for CY 2015; Proposed Rule

Dear Ms. Tavenner,

We appreciate the opportunity to provide comments in response to the MPFS proposed rule: 42 CFR Parts 403, 405, 410, 414, 425, and 498 which was published in the Federal Register/Vol. 79, No. 133 on July 11, 2014.

The Provider Roundtable (PRT) members are from 13 different health systems serving 18 states. PRT members are full-time employees of hospitals. As such, we have a financial interest in fair and proper payment for physician services under the MPFS.

The members collaborated to provide substantive comments with an operational focus that we hope CMS staff will consider during the annual MPFS policymaking process. We appreciate the opportunity to provide our comments to the agency. 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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PRT Chair and
Corporate Director, Health Information Management
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**Application of Beneficiary Cost Sharing to Anesthesia Related to Screening Colonoscopies**

Like CMS, the PRT recognizes the standard of care for screening colonoscopies is shifting from using moderate sedation to using anesthesia services provided by an anesthesia specialist. We share CMS' concerns about the resulting increase in patient cost-sharing stemming from this practice shift. To this end, we support the agency's proposal to revise the definition of colorectal cancer screening tests to include anesthesia that is separately furnished in conjunction with screening colonoscopies.

The PRT also agrees with CMS that a waiver of co-insurance and deductible be applied for these cases. Doing so will ensure both consistent policy and continued beneficiary access to screening benefits.

CMS notes that, if this proposal is finalized, the agency will have to establish a modifier for use when billing the relevant anesthesia codes for services furnished in conjunction with screening colonoscopy, in order to track that the waiver of Part B deductible and coinsurance is met. CMS states that the agency will provide appropriate and timely information on the new modifier and its proper use.

The PRT suggests that CMS adopt the use of a new modifier or other means that will ensure beneficiaries do not pay co-pays for either a screening colonoscopy or a screening colonoscopy that is converted to a diagnostic procedure.

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

The PRT seeks clarification on CMS' interest in gathering data on services delivered through off-campus provider-based locations, and its proposals for a collection process. We request that the agency clarify precisely what data CMS wishes to collect as well as how the agency intends to use these collected data. The PRT is greatly concerned about CMS' interest in unleashing this huge administrative burden upon providers.

We are uncertain whether CMS expects modifiers to be used *solely* for services that are rendered in off-campus provider-based departments. Additionally, we are unclear how CMS intends to track whether different services were provided in two *separate* provider-based off-campus locations on the same day, for the same beneficiary. Will CMS create modifiers to specifically track *each* address (or location) at which services are rendered? Or, is the agency's intent to collect data on whether some services were rendered off-campus, with unmodified services representing services that were delivered on-campus?

We believe that using a modifier is not the best methodology, due to the operational burden and confusion it will cause. Many states have different definitions of "off-campus" and providers may not understand how to correctly report the modifier for CMS' purposes. And, if CMS limits the modifier requirement to specific services, it will preclude the agency from truly tracking *all* costs associated with off-campus locations.

We firmly believe that creating modifier(s) to append to off-campus services will be not be

feasible from an operational perspective. Providers will have two options: either manually apply the modifiers, or set up specific line items in their Charge Master. The labor to replicate and maintain the unique line items in the Charge Master in order to report the modifier will consume additional resources as well as increase labor costs to manage this requirement.

We also note that lab, pharmacy, and other ancillary items are assigned to specific cost centers (and not charged or billed directly from an off-campus department's cost center); our information systems are not sophisticated enough to assign a charge line item *with* a specific modifier to identify off-campus location use as well as assigning a charge for the same line item *without* the modifier for onsite campus locations. There is no common denominator to use to program systems to identify the two different location types. These types of situations will require manual intervention to apply the modifier specifically for services provided in off-campus clinics, which will result in an enormous number of resources to operationalize.

We understand that the agency is interested in this information and seeks to collect these data. The PRT could not come to consensus on a methodology for doing so that would work for all members. Our difficulty stems from not understanding the agency's specific aim, since information about the frequency and type of services can be obtained from both professional and hospital claims. We did reach consensus on two suggestions for CMS associated with this issue:

1. In order to capture the information about what services are being billed as off-campus provider-based services, the best methodology would be to report a new place of service code specifically for off-campus provider based departments on the CMS-1500 form to capture the professional services information. CMS could then correlate the professional services to hospital claim for same patient and same date of service. This correlation would reflect the services and units were provided to the unique patient. Most UB-04 claims will have multiple services reported on the technical side, and one or more on the provider side (since hospital providers will have provided the services ordered by the physician in the off-campus clinic).

2. A second suggestion is to create a new bill type for off-campus site locations, if the issue of combining claims is addressed and approval from NUBC obtained. We note that CMS would have to review (and potentially revise) the requirement to combine all services on one claim (i.e., either off-campus or on-campus).

Hospitals are the hub of new models of care, and there are, inherently, more costs related to the hospital processes and services due to the range of services provided in this setting. The PRT is concerned that the data collected will be hugely flawed and do not understand the agency's intentions for using these data once they have been collected.

**Payment of Secondary Interpretation of Images**

CMS requested comments on a number of questions regarding the payment of secondary interpretation of images. The PRT is pleased to provide our feedback in this area.

While the PRT understands CMS' concerns regarding duplicative advanced imaging studies, in

speaking with our members, we have identified a number of considerations that may reduce the potential cost savings associated with expanded payment of secondary interpretations.

Often, repeat advanced imaging studies are performed to monitor a patient's changing condition. For example, in the case of a traumatic injury or cerebral vascular accident (CVA), a repeat study may be performed to monitor and/or diagnose a patient's rapidly changing clinical condition. In such cases, a secondary interpretation would *not* prevent a repeat study. This can also be true in the case of a diagnosed malignancy, where the treating facility to which the patient is referred may want the most current clinical picture of the patient's condition prior to determining an appropriate treatment regimen.

In cases where a patient's condition does not require a repeat study, expanded use of the electronic health record means the initial interpretation report is generally available. In fact, it is often more readily available than the study films, further limiting the potential of secondary interpretations to prevent duplicative studies. There is also the potential that such a policy could have the unintended consequence of actually *promoting* unnecessary secondary interpretations rather than reducing repeat imaging.

Nonetheless, the PRT recognizes that there may be situations in which the expanded payment of secondary interpretations could prevent repeat advanced imaging studies. We understand CMS' desire to ensure that payment for secondary interpretations promotes the intended purpose (i.e., reducing program costs by reducing the incidence of duplicative advanced imaging studies). Nonetheless, we are concerned about the operational burden that may be placed on providers in order to *demonstrate* to CMS that a secondary interpretation was in fact ordered and not just done routinely. We are also concerned that CMS may have an expectation that if a second interpretation is ordered that a repeat study would not be done, but as explained above that may not always be the case. Repeat imaging may in fact be needed after the second interpretation but this study should not be considered a duplicative or unnecessary study.

Given these issues, the PRT believes there are significant operational considerations arising from CMS' proposal to provide reimbursement for secondary interpretation of radiology images. We are not sure that adoption of more liberal payment for secondary interpretations will, in fact, reduce duplicative imaging studies in a meaningful way.

Because of the many outstanding questions surrounding this proposal, the PRT suggests that CMS conduct a demonstration to study the issue. Such a demonstration would allow the agency to analyze the viability of the proposed payment change, and simultaneously assess the most efficient method of implementation.

**Local Coverage Determination Process Change for Clinical Diagnostic Laboratory Testing**

The PRT understands and supports CMS' desire to promote a more efficient local coverage determination (LCD) process particularly given the rapid growth and use of molecular diagnostic tests. However, we do not support the reduction of the initial public comment period from 45 calendar days to 30 calendar days.

Also, we cannot support the change in the effective date of the final LCD to be the date of publication for the following reasons:

1. Providers need time to prepare staff and internal operational systems to appropriately respond to the changes and challenges presented by new coverage policies. New coverage policies require the education of staff, the creation of new edits in hospital registration and billing systems, the addition of the new LCD to the organization's ABN process, outreach to physicians regarding the new coverage requirements, and the education of patients regarding the potential financial consequences of the new coverage policy. In addition, we are dependent on our vendors who require time to program systems and push out the results to us for use. Based on our experience with them for updating other systems, this will take a minimum of forty-five (45) days.

2. It is common for the final determination to be very different from the proposed document as providers and others take time to comment on the topic under consideration. For this reason, providers are not able to adequately prepare for a new LCD based upon the draft policy alone and must wait until the final coverage document is issued to finalize its preparations. To prepare operational processes based on the proposed determination and then to have to change these based on the final LCD requires double effort and twice the number of resources for providers.

3. The typical policy process customarily allows providers time to review and implement policy changes. For example, the rule making processes include a proposed rule, comment period, final rule, and time for implementation prior to the effective date. We do not understand why CMS would deviate from this framework with regards to the LCD process.

In addition, and as consistent with the Protecting Access to Medicare Act (PAMA), we encourage CMS to more actively promote consistent laboratory coverage policies across jurisdictions. CMS should utilize the National Coverage Determination (NCD) process in lieu of the LCD process to insure coverage policies for laboratory tests, including molecular diagnostics, are consistent with recognized indications applicable to Medicare beneficiaries across all jurisdictions. When LCDs are inconsistent across jurisdictions, the policies produce coverage inconsistencies and reduced access to valuable clinical laboratory tests to certain Medicare beneficiaries.

The PRT does agree with changing the requirement regarding submitting the draft LCD policy to the Carrier Advisory Committee (CAC) from mandatory to optional.

**Telehealth Services**

Telehealth capabilities have greatly expanded in recent years, and will continue to do so. We recognize that telehealth services are, by definition, furnished by an interactive telecommunications system that allows two-way, real-time interactive communication between the patient and the distant-site physician or practitioner. These services have the capacity to greatly benefit patient health, particularly for individuals who live in rural areas and areas

suffering from provider shortages.

The PRT supports CMS' on-going consideration of the list of approved telehealth services including those recommended in the Proposed Rule. Given the advances in this technology, the PRT believes that telehealth is an appropriate and efficient means to provide care to communities that have limited coverage from health care providers (including physician and non-physician providers).

In addition, due to the advances in telehealth, the PRT believes the time has come for CMS to consider the use of telehealth for the purpose of direct supervision of certain therapeutic outpatient services. The PRT understands that telecommunication by phone does not fulfill the requirements of direct supervision, that the physician be considered physically present and immediately available. We believe, however, that, with the advances of telehealth technology, the real-time interactive communication between the patient and distant-site physician would qualify for face-to-face visit. We believe, therefore, that it could also serve as a mechanism for physician supervision in the future.

Many members of the PRT have telehealth services capabilities that provide physician support for various emergent conditions such as e-Emergency and e-Stroke programs. We believe the telehealth advances should allow providers the opportunity to utilize these high tech services for physician supervision of therapeutic services. We note that 75 FR 72008 states: "We do not see how a practitioner who is only remotely available by phone or other means of telecommunication could fulfill these requirements and, therefore, we do no not consider availability by means of telecommunication to be an acceptable means of providing direct supervision. However, this issue might potentially be considered by the independent panel in future years."

The PRT believes that telehealth meets the definition of "immediately available" based on meeting the face-to-face requirements through technological advances, which enable equipment to be able to focus on the smallest details such as the cornea of the eye. These services were specifically designed to care for patients in remote locations where physicians or physician specialties are limited.

Telehealth provides for "immediate" support from an advanced practitioner at a distant site who can support the care of a patient in a remote location for very serious indications. It seems reasonable to the PRT that telehealth could *also* serve as direct supervision for specific therapeutic services, such as chemotherapy, that are delivered in rural settings. The PRT believes the criteria for being "immediately available and physically present" is comparable to the coverage that is currently allowed under telehealth regulations; these regulations allow physicians to bill telehealth as face-to-face encounters due to technological advancements.

The PRT believes that the use of telehealth for direct supervision will increase providers' flexibility in ensuring the correct level of supervision, and also improve Medicare beneficiaries' access to valuable outpatient therapeutic services. For this reason, the PRT respectfully requests that CMS consider the modality of telehealth as a way to meet the requirements for physicians to be "immediately available" to provide direct supervision for certain therapeutic services.

**Solicitation of Comments on the Payment Policy for Substitute Physician Billing Arrangements**

The PRT understands that CMS seeks comments regarding substitute physician billing arrangements. We understand that the agency is concerned about operational and program integrity issues resulting from the use of substitute physicians to support staffing needs and/or replace a physician who has permanently left a medical group or employer.

The PRT is please to provide comments to CMS regarding this issue. We believe that adopting our suggestions will promote greater transparency and integrity when providers, such as hospitals, use substitute physicians to support their staffing needs.

*(1) How are physician and other entities currently utilizing the services of substitute physicians and billing for such services?*

The PRT notes that substitute physicians are often used to fill in during staff vacations, medical and/or maternity leaves, continuing medical education, and unexpected departures. They are also used to fill temporary staffing needs, such as to replace physicians who have permanently left the practice.

While providers enter into a locum arrangement expecting it to be a temporary situation lasting less than 60 days, it is not unusual for the need for the locum to extend beyond that time frame due to difficulties in staff recruitment and placement. As a result, the PRT would appreciate CMS extending the time frame for locum use, as long as the agency also creates a mechanism to identify the locum physician with the NPI on the claim for full transparency.

*(2) When is a physician "unavailable"?*

The PRT comments that this is hard to define, since the vacancies stem from a variety of reasons, as noted above. The causes range from medical and maternity leave, vacations, departures from practices, and on-going physician shortages.

*(3) Should hospitals be limited to substitute physician billing arrangements "between the two physicians" rather than between a medical group, employer, or other entity and the substitute physician?*

While limiting substitute physician billing arrangements to those that occur between two physicians is appropriate for reciprocal arrangements, the PRT does not agree that locum arrangements should be *limited* to those between the two physicians. We strongly believe that such a limitation will compromise patient access to both physicians and high-quality care. It would also limit coverage options for physicians, including temporary replacement of hospital-based physicians employed by health care providers such as a hospital or CAH.

*(4) Should CMS permit the sequential use of multiple substitute physicians, provided that each substitute physician furnishes services for the unavailable physician for no more than 60 continuous days?*

The PRT supports CMS permitting the sequential use of multiple substitute physicians. We also believe that providers should be able to utilize the same locum physician for longer than 60 days in the event the provider is unable to recruit and place a qualified permanent physician within that time frame (as noted above). We understand, however, that CMS is concerned about ensuring program integrity; to this end, we recommend that CMS adopt a mechanism to identify substitute physicians on the 1500 claim form.

*(5) Should CMS have identical or different criteria for substitute physician billing arrangements for reciprocal vs. locum tenens substitute physicians?*

The PRT has no comment on this issue.

*(6) Should substitute physicians be required to enroll in the Medicare program?*

We do not believe substitute physicians necessarily need to be enrolled in the Medicare program as long as the substitute physician's NPI is noted on the claim form.

*(7) Should entities submitting claims for services furnished by substitute physician include on the CMS-1500 claim form, or on the appropriate electronic claim form, the identity of the substitute physician?*

As noted above, the PRT supports the identification of the substitute physician on the CMS-1500 form, so long as that form is edited to accommodate such a requirement. We believe that this would provide the transparency needed to promote the Medicare program's integrity.

*(8) Should there be limits on the use of the substitute physician and billing for his or her services based on the overall length of time that a substitute physician may provide services to replace a particular departed physician?*

In our experience, circumstances often arise that require the need for substitute physicians over an extended period of time both in facilities located in physician shortage areas for specific specialties, as well as in facility practices that face challenges in recruiting and placing qualified physicians. We believe the provider community should not face limitations in our efforts to access qualified physicians to provide coverage and high-quality care to patients in our communities. Limiting providers' use of substitute physician services will harm beneficiaries and burden community providers that are attempting to address physician shortages.

*(9) Should we limit or prohibit the use of substitute physician billing arrangements in certain programs or for certain purposes?*

The PRT opposes the application of such limitations on substitute physicians for special programs (i.e., Medicare Shared Savings Program). We do not believe that this is necessary in order to prevent self-referral abuses. As stated above, the creation of a mechanism to identify the substitute physician on the claim is a better mechanism for addressing that concern.

*(10) What is the impact of substitute physician billing arrangements on CMS programs that rely on the Provider Enrollments, Chain and Ownership System (PECOS) and (11) What additional program integrity safeguards should be included in our substitute physician billing policy to protect against program and patient abuse?*

The PRT supports implementing program integrity safeguards for substitute physician billing in a manner that is meaningful and does not hamper provider's efforts to secure substitute physicians when necessary. Providers should be held accountable for credentialing, which should include exclusion status, quality of care, licensure, and certifications.

**Reports of Payments or Other Transfers of Value to Covered Recipients**

The PRT supports CMS' proposal to remove the language in § 403.904(g) and concurs with the agencies' rationale. We agree with CMS that the exception to reporting payments for physician speakers at certain continuing education programs inadvertently endorses certain accrediting organizations. We find this both confusing and redundant, given the exclusion in § 403.904(i)(1).

CMS proposes two alternatives, but the PRT does not believe either is viable, for the specific reasons CMS itself notes: the unintended endorsement of selected continuing education providers, and the difficulty of enforcing continuing education provider standards. We also believe the proposed alternatives are unnecessary. The language already included in §403.904(i)(1) is adequate for the purposes of the continuing education exemption (i.e., the manufacturer is unaware or does not know the identity of the covered recipient).

The PRT does believe, however, that CMS must clarify circumstances where payments are excluded from reporting requirements. In the Proposed Rule, CMS states that, when an applicable manufacturer (or applicable GPO) provides funding to a continuing education provider but does not either select or pay the covered recipient speaker directly, or provide the continuing education provider with a distinct and identifiable set of covered recipients to be considered as program speakers, these payments are excluded from reporting requirements.

The PRT requests that CMS expand this statement and specifically exempt the payment *even if* the applicable manufacturer (or applicable GPO) becomes aware of the identity of the recipient through incidental or other means (i.e., a published program brochure). We do not believe that incidental knowledge of the covered recipient is sufficient grounds to nullify the exception.

If the applicable manufacturer (or applicable GPO) conditions the payment to the continuing education provider on the selection of a *specific* physician speaker, or gives the provider a distinct and identifiable set of covered recipients to serve as the speaker(s), it is consistent with the Open Payments program intent for these payments to be disclosed. Again, CMS should be clear in its regulatory language that this is its intent.

With regard to CMS' other Open Payments proposals, the PRT supports the proposal to require the reporting of the marketed name of all covered and non-covered drugs, devices, biologicals, or medical supplies in order to promote reporting consistency and transparency. For the same reason, we also support reporting stock and stock options as distinct categories.

## Attachment A: 2014 Provider Roundtable Members

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